No. 2015-1067

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

INOVA LABS, INC.

Appellant

v.

INOGEN, INC.,

Appellee

Appeal from the United States Patent and Trademark Office
Patent Trial and Appeal Board
In Reexamination No. 95/001,885

APPELLANT BRIEF

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Inova Labs, Inc. v. Inogen, Inc.

No. 15-1067

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) appellant certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Inova Labs, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Inova Labs, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. ☑ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Eric B. Meyertons
Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C.

12/19/2014
Date

/s/Eric B. Meyertons
Signature of counsel

Eric B. Meyertons
Printed name of counsel

Please Note: All questions must be answered
cc: Appellee's counsel of record (via CM/ECF)

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denied, 493 U.S. 975 (1989).

Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987).

Upsher-Smith Labs. v. Pamlab, LLC, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005).

STATEMENT OF RELATED CASES

The Appellant is unaware of any related appeals pending before the Court. The Patent Owner alleges that Appellant's oxygen concentrator infringes U.S. Patent No. 7,841,343 and U.S. Patent No. 6,790,260, both of which are under reexamination, in the United States District Court for the Central District of California, in the case of Inogen, Inc. v. Inova Labs, Inc., Court Case No. SACV11-1692 JST (ANx). The court has stayed the case for the purpose of reexamination.

JURISDICTIONAL STATEMENT

This Court has jurisdiction to hear Appellant's appeal pursuant to 15 U.S.C. § 1071(a). Appellant/Inova Labs requested reexamination of U.S. Patent No. 7,841,343 to Deane et al. ("Deane") on March 1, 2012. On July 1, 2014, Patent Trial and Appeal Board (hereinafter the "PTAB") rendered a Decision on Appeal upholding the validity of claims 1-3 and 8-20. No rehearing has been granted, and thus the Decision on Appeal of the PTAB is final and appealable pursuant to 37 C.F.R. §§ 90.2(a)(1), 90.1, and 1.983. A Petition for Review of the Decision on

Appeal of the PTAB was timely filed with this Court as well as the Director of the Patent and Trademark Office on September 5, 2014, pursuant to 35 U.S.C. § 142.

STATEMENT OF ISSUES

Only one issue is being presented to the Court to simply the matters under consideration, whether claims 1-3 are unpatentable under 35 U.S.C. §103(a) over Hakkinen in view of Admitted Prior Art (hereinafter "APA"). This issue was raised in the Request for Reexamination of Deane. The PTAB, in the Decision of Appeal, affirmed the Examiner's non-adoption of this rejection of claims 1-3. Decision, pg. 2, App. pg. 18. The patentability of claims 4-20 is not being contested at this time to simplify matters and because Appellant does not infringe any of claims 4-20.

STATEMENT OF THE CASE

In the *Inter Partes* Reexamination on U.S. Patent No. 7,841,343, Appellant requested that claims 1-3 be found unpatentable under 35 U.S.C. §103(a) over

Hakkinen in view of Admitted Prior Art (hereinafter "APA"). In the Decision of Appeal, the PTAB affirmed that claims 1-3 were patentable over the cited art. Appellant requests the reversal of the PTAB's ruling on the grounds that it improperly applied legal standards of obviousness in ascertaining the scope of the prior art's teachings.

STATEMENT OF THE FACTS

Claim 1 of Deane is directed to a system for delivering therapeutic gas (e.g., oxygen) to patients. The system of claim 1 includes components such as: a gas source; a conserver that is used to deliver gas from the gas source to the patient; a sensor for detecting breath pressure level; and a processor and control elements for controlling the delivery of gas to the patient. The system of claim 1 also includes the feature whereby a selected threshold breath pressure level detected by the sensor triggers the processor and control elements to deliver a volume of gas to the patient. All of these features are set forth in U.S. Patent No. 4,986,269 to Hakkinen ("Hakkinen").

Claim 1 of Deane also includes the feature that threshold pressure levels should be set at a lower level adapted to trigger delivery of gas to the user when the

user is asleep or in a state of inactivity such that the user's breath is shallower than normal. This feature is taught in the prior art including the Admitted Prior Art (the "APA") set forth in Deane.

Claim 1 also teaches that the threshold breath pressure level detected by the sensor is user selectable. Hakkinen teaches the use of a device (a potentiometer) that is used to select (and adjust) the threshold breath pressure level detected by a sensor. A potentiometer is usually just a knob (like on a radio or TV to adjust volume) that is used to adjust a setting. Hakkinen does not impose any limitations whatsoever as to who can use the potentiometer in Hakkinen to adjust the threshold breath pressure setting.

SUMMARY OF THE ARGUMENT

Claim 1 of Deane describes a system for delivering for therapeutic breathing gas to a patient that includes: a gas source; a conserver between the gas source and the patient; a sensor for detecting patient breath events and measuring the parameters of the breath events, said parameters including breath pressure level; and a processor and control elements for acquiring signals from the sensor and controlling the delivery of gas to the patient. Hakkinen teaches a system for

delivering therapeutic breathing gas to a patient. The system of Hakkinen includes: a gas source; a conserver between the gas source and the patient; a sensor for detecting patient breath events and measuring the parameters of the breath events, said parameters including breath pressure level; and a processor and control elements for acquiring signals from the sensor and controlling the delivery of gas to the patient.

Claim 1 of Deane also teaches that the system supports at least one mode of operation such that a threshold breath pressure level detected by the sensor, which causes the processor and control elements to deliver a volume of gas to the patient, is selectable such that the volume of gas is delivered to the patient when the patient's threshold breath pressure level is at the level selected by the user. Hakkinen teaches that the use of a device (a potentiometer) that is used to select and control the sensitivity of a sensor that detects the breath pressure level, and Hakkinen never places any limits upon who can use such potentiometer.

Claim 1 of Deane also teaches that the system includes a plurality of user selectable threshold pressure levels, said threshold pressure levels comprising a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal. The need for allowing the user to lower the threshold pressure levels is not discussed in

Hakkinen, however it was well known that threshold pressure levels of a patient are lower at night (in fact, this is common sense). In fact, Deane teaches and admits that that it was well known at the time of the invention (and thus APA) that: (1) during sleep, the patient's breathing generates lower breath pressure, requiring the need for a lower breath pressure threshold in order to accurately detect breathing when the patient is asleep; (2) a lowered breath pressure threshold, while needed during sleep, is not desired during normal daytime patient activity, and (3) the inhalation breath pressure level setting should not be set too high or too low. Thus, it would have been obvious, at the time of the invention, to alter the nighttime threshold pressure levels of the system of Hakkinen (using the disclosed potentiometer in Hakkinen) in view of the APA.

While neither Hakkinen nor the APA explicitly teaches that the threshold pressure levels are "user selectable," Hakkinen does teach that the threshold pressure levels can be controlled, and includes a potentiometer to do so. Hakkinen also teaches that it is well known in the art that external devices (such as buttons) can be used to alter the operating parameters of a conserving device. Moreover, there are no limits as to who can use the potentiometer (e.g., knob) disclosed in Hakkinen in order to control threshold pressure levels. Allowing the user to switch the threshold breath pressure level to a lower level, however, will be the most

efficient way of ensuring that the threshold breath pressure level is used during nocturnal sleep.

For the hypothetical person of ordinary skill in the art, when confronted with the problem of ensuring that the breath pressure threshold is set to the appropriate sensitivity when the patient is sleeping, it would have been obvious to allow a user to use the potentiometer in Hakkinen to allow the user to adjust the sensitivity. The motivation to do so is provided by the APA which teaches that the breath pressure threshold level should be lowered to ensure that the therapeutic gas is delivered to the patient when the patient is sleeping.

In sum, Hakkinen teaches all of the system/apparatus features of claim 1. If a user operated the Hakkinen system at night then such user would have been able to perform all of the features of claim 1 without any modifications at all to the Hakkinent system/apparatus. As such, it would be obvious to allow a user to use the system of Hakkinen to control and select nighttime threshold breath pressure levels, especially since Hakkinen does not put any limits upon who can use the potentiometer of Hakkinen, and especially since the APA provides the specific motivation to do so.

ARGUMENT

I. Summary of Claims 1-3 of Deane

U.S. Patent No. 7,841,343 to Deane et al. ("Deane") was filed on June 6, 2005 and claims priority to U.S. Provisional Patent Application No. 60/577,088, filed on June 4, 2004.

Deane describes a system for delivering for therapeutic breathing gas to a patient. Claim 1 of Deane states:

> 1. A system for delivering therapeutic breathing gas to a patient, comprising:
>
> a gas source;
>
> a conserver between the gas source and the patient;
>
> a sensor for detecting patient breath events and measuring the parameters of the breath events, said parameters including breath pressure level;
>
> processor and control elements for acquiring signals from the sensor and controlling the delivery of gas to the patient,
>
> wherein the system supports at least one mode of operation such that a threshold breath pressure level detected by the sensor, which causes the processor and control elements to deliver a volume of gas to the patient, may be user selectable such that the volume of gas is delivered to the patient when the patient's threshold breath pressure level is at the level selected by the user; and
>
> wherein the system provides a plurality of user selectable threshold pressure levels, said threshold pressure levels

> comprising a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal.

See App. pg. 16. Deane teaches that a gas source may be an oxygen source. Exemplary oxygen sources include an oxygen concentrator or a high pressure oxygen tank. See Deane, Col. 5, lines 46-48, App. pg. 14; see also claim 3, App. pg. 16. With respect to the conserver, Deane teaches:

> The conserver, many designs of which are known in the art, senses a patient's breath demand, and responds by delivering a volume of oxygen-rich gas (known as a bolus) to the patient.

Deane, Col. 1, lines 33-35, App. pg. 12.

The system of claim 1 also includes "a sensor for detecting patient breath events and measuring the parameters of the breath events." Deane does not give any specific examples of sensors, nor does Deane define or limit the phrase "parameters of the breath events." Claim 1, however, requires that the parameters of the breath events includes "breath pressure level."

Claim 1 also includes processor and control elements for acquiring signals from the sensor and controlling the delivery of gas to the patient. The processer and control elements are used to control the delivery of gas to the user. The processor and control elements "deliver a volume of gas the patient." The gas is "delivered to the patient when the patient's threshold breath pressure level is at the

level selected by the user."

The phrase "threshold breath pressure level" is not defined by Deane. Deane, however, teaches that:

> Typically, a conserving device triggers a bolus delivery when it detects a predetermined inspiratory pressure from the breath sensor. Thus, the term "threshold pressure" generally refers to the sensed inspiratory pressure at which a bolus delivery is triggered.

Deane, Col. 6, lines 11-14, App. pg. 14. Based on the teachings of Deane, the "threshold breath pressure level" set forth in claim 1 is related to the "threshold pressure" defined in the specification.

Claim 1 also includes the feature that the system provides a plurality of user selectable threshold pressure levels. The plurality of user selectable threshold pressure levels includes "a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity."

Claim 2 further limits claims 1 by requiring that the different levels of threshold breath pressure comprise two user-selectable levels, representing a night mode and a day mode, and the actual values of each level are determined by the patient's caregiver.

Claim 3 further limits claim 1 by requiring that the gas is oxygen and the gas source is an oxygen concentrator.

II. Claims 1-3 Of Deane Are Obvious In View Of The Prior Art

Claims 1-3 are obvious in view of U.S. Patent No. 4,986,269 to Hakkinen ("Hakkinen") in view of the Admitted Prior Art (hereinafter "APA") that appears in the background section of Deane.

Hakkinen describes a system for delivering therapeutic breathing gas to a patient. See Hakkinen, col. 1, lines 14-19 (emphasis added); see also FIG 7A. Hakkinen also describes a gas source. See Hakkinen, col. 5, lines 35-44, App. pg. 47; see also FIG. 7A, App. pg. 41.

Deane admits a conserver is known in the art. Deane states:

> The conserver, many designs of which are known in the art, senses a patient's breath demand, and responds by delivering a volume of oxygen-rich gas (known as a bolus) to the patient."

Deane, col. 1, lines 33-35, App. pg. 12. Thus, Deane admits that a conserver is prior art and defines a conserver as a device that senses a patient's breath demand and responds by delivering a volume of oxygen-rich gas to the patient.

Hakkinen describes an automated valve between the gas source and the patient. Hakkinen states:

> At commencement of the inspiration phase, the differential pressure is transmitted over a signal connection (99) to the pressure pick-up (22). The pressure pick-up (22) further controls the electromagnetic valve (23), opening the pressure line (16). The pressure pick-up (22) measuring differential pressure has been connected, in accordance

> with the present invention, over a signal connection (19, 39, 59 or 99) to an oxygen mask, to oxygen whiskers (30), to an atomizer (50), or to a respirator (80).

Hakkinen, abstract (emphasis added) App. pg. 36. Hakkinen also states:

> This pick-up indicating the pressure of the respiration flow, is further applied to control a control valve which governs the oxygen or air flow going to the patient.

Hakkinen, col. 2, lines 39-42, App. pg. 45.

Deane defines a conserver as a device used to sense a user's breath demand, and deliver a volume of oxygen-rich gas to the patient. The above-described valve system, sensors, and control unit 14 of Hakkinen represents a conserver. Thus, Hakkinen teaches a conserver.

Hakkinen describes a sensor that detects patient breath events and measuring the parameters of the breath events including breath pressure level. Hakkinen also describes a processor and control elements for acquiring signals from the sensor and controlling the delivery of gas to the patient. Hakkinen states:

> Through a connector 1.5 of a pressure hose of a sensor in the injector 1.3, variations of the breathing pressure are conducted into a pressure transmitter or pressure pick-up 2. A voltage message is obtained from the pressure transmitter 2, the size of the message being dependent upon the value of breathing pressure. The voltage message to be obtained in the inhalation phase is guided to a triggering circuit 3, the triggering sensitivity of which can be controlled by means of a potentiometer 3.1. The trigger pulse sets the trigger output of an RS-flip-flop 5 to the upper position. This signal is reinforced in a circuit

> 6 controlling the pressurized air entering the injector 1.3 by means of a magnet valve 7. The same pulse triggers a timer 8 which guides the magnet valve 10 of the spraying pressure.

Hakkinen, col. 10, lines 8-28, App. pg. 49. The triggering circuit 3 in Hakkinen includes processor and control elements. As described above, and as shown in Figures 8, 9, and 10, the user's inhalation breathing pressure is obtained from a pressure sensor, converted to voltage, and this voltage is sent to a triggering circuit. The triggering circuit, when triggered, causes air and/or oxygen to be provided to the user. Thus, the triggering circuit set forth above includes "processor and control elements for acquiring signals from the sensor and controlling the delivery of gas to the patient."

Hakkinen also teaches that the threshold breath pressure level is adjustable. For example, Hakkinen teaches:

> Through a connector 1.5 of a pressure hose of a sensor in the injector 1.3, variations of the breathing pressure are conducted into a pressure transmitter or pressure pick-up 2. A voltage message is obtained from the pressure transmitter 2, the size of the message being dependent upon the value of breathing pressure. The voltage message to be obtained in the inhalation phase is guided to a triggering circuit 3, **the triggering sensitivity of which can be controlled by means of a potentiometer 3.1**.

Hakkinen, col. 10, lines 8-17 (emphasis added); see also Hakkinen FIGs. 8, 9, and 10, App. pgs. 42-44, 49.

> The computer may equally be programmed to operate the respiration therapy apparatus of the invention, in a manner such that with the aid of a program stored in the computer's memory, **the therapeutic variables of the respiration therapy apparatus**, such as respiration pressure, drug atomizing, etc., **are controlled**.

Hakkinen, col. 8, line 68 through col. 9, line 6, App. pg. 48 (emphasis added). Thus, Hakkinen teaches a system that includes all of the components of the system described in claim 1. Specifically, Hakkinen teaches: a gas source; a conserver, a sensor, and processor and control elements. Hakkinen also describes a potentiometer that can alter the triggering sensitivity (i.e., the threshold breath pressure level) of the system.

Hakkinen does not specifically teach that the need to set the threshold breath pressure level to a lower level when the user is asleep or in a state of inactivity. However, it was well known at the time of the invention that the threshold breath pressure level changes during sleep or states of inactivity. For example, Deane discloses, in the section entitled "Description of the Related Art":

> One cause for this nighttime desaturation concern surrounds the conserver's sensitivity, or the inhalation vacuum pressure (typically sensed through a nasal cannula) that results in a bolus delivery. In order to reduce false triggers (bolus delivery when no breath has occurred), breath detection, which is accomplished by measuring inhalation vacuum pressure typically through a nasal cannula, is set to a level corresponding to normal daytime breathing and activity patterns. If the pressure at which the conserver triggers a bolus is too

> low, normal activity may cause false firing, which can be disconcerting to patients and is ineffective oxygen therapy as much of this oxygen does not reach the lungs. However if the trigger pressure is too high, the conserver does not recognize a breath until a significant portion of it has already been inspired, which reduces the efficacy of the delivered bolus. Thus, it is desirable to have the conserver's breath sensitivity be as high as possible such that bolus delivery speed is accelerated, so long as this sensitivity remains low enough to avoid activity-induced false firing.

Deane, Col. 1, line 65 – Col. 2, line 15, App. pg. 12.

> Moreover, during sleep, some patients are shallow and/or irregular breathers, such that nighttime breathing for these patients may not generate enough vacuum pressure to trigger bolus delivery.

Deane, Col. 2, lines 21-24, App. pg. 12.

Deane discloses, in the section entitled "Description of the Related Art":

> One cause for this nighttime desaturation concern surrounds the conserver's sensitivity, or the inhalation vacuum pressure (typically sensed through a nasal cannula) that results in a bolus delivery. In order to reduce false triggers (bolus delivery when no breath has occurred), breath detection, which is accomplished by measuring inhalation vacuum pressure typically through a nasal cannula, is set to a level corresponding to normal daytime breathing and activity patterns. If the pressure at which the conserver triggers a bolus is too low, normal activity may cause false firing, which can be disconcerting to patients and is ineffective oxygen therapy as much of this oxygen does not reach the lungs. However if the trigger pressure is too high, the conserver does not recognize a breath until a significant portion of it has already been inspired, which reduces the efficacy of the delivered bolus. Thus, it is desirable to have the conserver's breath sensitivity be as high as possible such that bolus delivery speed is accelerated, so long as this sensitivity remains low enough to avoid activity-induced false firing.

Deane, Col. 1, line 65 – Col. 2, line 15, App. pg. 12.

> Moreover, during sleep, some patients are shallow and/or irregular breathers, such that nighttime breathing for these patients may not generate enough vacuum pressure to trigger bolus delivery.

Deane, Col. 2, lines 21–24, App. pg. 12.

The APA is in the "Background of the Invention" section of the '343 patent and the APA constitutes a prior art admission. The APA discloses that it was well known at the time of the invention that: (1) during sleep, the patient's breathing generates lower breath pressure, requiring the need for a lower breath pressure threshold in order to accurately detect breathing when the patient is asleep; (2) a lowered breath pressure threshold, while needed during sleep, is not desired during normal daytime patient activity, and (3) the inhalation breath pressure level setting should not be set too high or too low.

Furthermore, what was admitted as prior art in the APA is, indeed, already known in the art. For example, U.S. Patent Application Publication No. 2003/0140924 to Aylsworth et al. ("Aylsworth") describes that during sleep, the patient's breathing generates lower breath pressure, requiring the need for a lower breath pressure threshold in order to accurately detect breathing when the patient is asleep. See Aylsworth, paragraph [0062] - [0064], App. pg. 84. Aylsworth also

discusses how a lowered breath threshold, while needed during sleep, is not desired during daytime patient activity. See Aylsworth, paragraph [0076] - [0077], App. pg. 85.

Thus, based on the teaching of the APA (or Aylsworth) and given that Hakkinen's potentiometer enables the user to adjust the threshold breath pressure level, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the potentiometer of Hakkinen to set the breath pressure threshold to a lower level during sleep and to a higher level during normal daytime activity, thereby ensuring that the oxygen delivery system will provide both accurate breath detection during sleep as well as efficient oxygen delivery during normal activity.

Hakkinen does not specifically teach a plurality of user selectable threshold pressure levels that include a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal. But Hakkinen does not need to do so. In fact, Hakkinen put no limits at all as to who could use the potentiometer taught in Hakkinen. Moreover, it was well known at the time of the invention of the need to lower the threshold breath pressure level when the user is asleep or in a state of inactivity.

In blunt terms, Hakkinen teaches, without any limits at all, that his

potentiometer can be used to control threshold breath pressure levels, and a simple reading of this teaching means that any person could use the Hakkinen system (including users) at any time (including at nighttime). As stated in the Declaration of William (Bill) Wilkinson under 37 C.F.R. §1.132 (the "Wilkinson Declaration") a potentiometer is device that enables a user to control an electrical device. For example, the Wilkinson Declaration states:

> Potentiometers are well known and are used by end users. A potentiometer is a device (e.g., a knob such as the knob on a TV, radio, or a dimmer control for a light) that is used to control electrical devices. Webster's New World College Dictionary, 2000, defines a potentiometer as "any various devices for measuring, comparing, or controlling electric potentials; specif., a kind of resistor that can be varied as in a rotary device used to control the volume of a radio, TV, etc."

Wilkinson Declaration, paragraph 12, App. pg. 96.

It would have been obvious to a person of ordinary skill in the art to use a user selectable potentiometer in the system of Hakkinen. Additionally, Hakkinen teaches that it is well known in the art that external devices (such as buttons) can be used to alter the operating parameters of a conserving device. For example, Hakkinen teaches that:

> Regulating valves are known in the art through which the air or oxygen can be conducted. It is possible with the aid of electrically controlled magnetic valves, or of magnetic valve controlling means, to effect control of the operating period of the respiration therapy

> apparatus in conformity with the patient's breathing rhythm. Similarly, it is possible with the aid of separate timer means to effect regulation of the resting period of the respiration therapy apparatus to conform to the patient's breathing rhythm.
>
> Respiration therapy apparatus of the prior art can then be controlled with the aid of press buttons or the equivalent in a manner such that the operation of the respirator is paced to be appropriate for the patient, for instance specifically by pressing a button.

Hakkinen, col. 1, lines 46-61, App. pg. 45.

The APA (and Aylsworth) teach that there is need for a lower breath pressure threshold in order to accurately detect breathing when the patient is asleep. It is obvious that the user will be aware that they are going to go to bed to sleep. Allowing the user to switch the threshold breath pressure level to a lower level is obviously the most efficient way of ensuring that the threshold breath pressure level is used during nocturnal sleep. For the hypothetical person of ordinary skill in the art, when confronted with the problem of ensuring that the breath pressure threshold is set to the appropriate sensitivity when the patient is sleeping, using the device of Hakkinen as is (by adjusting the potentiometer) to allow the user to adjust the sensitivity is an obvious approach to take.

In the alternative, it would be have been trivial to include a button on Hakkinen that was specifically directed to nighttime use of the Hakkinen potentiometer. The motivation for this modification is provided by the APA which

teaches that the breath pressure threshold level should be lowered to ensure that the therapeutic gas is delivered to the patient when the patient is sleeping. Thus, the combination of Hakkinen with the APA teaches all of the features of claim 1, and therefore claim 1 should have been considered obvious in view of the prior art by the PTAB.

Claim 2 includes the feature that the different levels of threshold breath pressure comprise two user-selectable levels, representing a night mode and a day mode, and the actual values of each level are determined by the patient's caregiver. As noted above, the APA (and Aylsworth) teach that the threshold breath pressure changes when the user is active, compared to when the user is asleep or resting. The system of Hakkinen is directed to providing supplemental oxygen to a user that is based on the patient's respiration. For example, Hakkinen teaches that:

> The present invention concerns a respiration therapy apparatus intended for persons suffering from respiratory diseases, for indisposed persons, or for unconscious persons, and employed as a respirator and/or as a drug atomizing apparatus and/or as an oxygen dispensing apparatus conforming to the patient's respiration.

Hakkinen, Col. 1, lines 14-19, App. pg. 45. Hakkinen also teach that a computer can be used to control the therapeutic variables of the respiration therapy apparatus. See Hakkinen, Col. 8, line 62 – Col. 9, line 12, App. pgs. 48-49. A computer as described in Hakkinen can be used to alter therapeutic variables (such

as threshold breath pressure) by a caregiver. For at least these reasons, and the reasons cited above, claim 2 is obvious in view of the cited art.

Claim 3 includes the feature that the gas is oxygen and the gas source is an oxygen concentrator. Deane teaches that use of an oxygen concentrator as an oxygen gas source is well known in the prior art. See Deane, col. 1, lines 18-31, App. pg. 12. Hakkinen teaches using a conserver between an oxygen source and a patient. Since the use of an oxygen concentrator as a gas source is admitted prior art to Deane, it would be obvious to use an oxygen concentrator as the oxygen source in the system of Hakkinen.

III. Patent Owners Arguments/USPTO Decision

In response to the rejections of the claims 1-3, Patent Owner made arguments that claims were patentable over the cited art. The Patent Owner argued that the potentiometer described in Hakkinen was intended to be used by the manufacturer to tune and fix the sensitivity of the triggering circuit at the factory. The Patent Owner provided two declarations in support of this argument.

One of the declarations presented is the declaration of Taisto Hakkinen (the "Hakkinen Declaration"). With regard to the potentiometer, Mr. Hakkinen states:

> I am the sole inventor of the subject matter disclosed in the [Hakkinen] Patent. The purpose of the potentiometer disclosed in my patent was to tune the sensitivity of the triggering circuit. The potentiometer provides a continuous range of variable resistance.

Hakkinen Declaration, paragraph 11, App. pg. 104.

It is important to note that the cited portion of the Hakkinen Declaration does not mention that the potentiometer is intended to be used to "fix the sensitivity of the triggering circuit at the factory." Hakkinen only states that the potentiometer is used to "tune" the sensitivity of the triggering circuit. When looking at the specification of Hakkinen, the potentiometer is referred to as element (3.1) in FIGS. 8 and 9, and as element (3.3) in FIG. 10. See Hakkinen, FIGS, 8, 9, and 10, App. pgs. 42-44. The potentiometer is electrically coupled to pressure transmitter (2.) in FIG. 10. See Hakkinen, FIG. 10, App. pg. 44. The specification of Hakkinen states that:

> A voltage message is obtained from the pressure transmitter 2, the size of the message being dependent upon the value of breathing pressure. The voltage message to be obtained in the inhalation phase is guided to a triggering circuit 3, the triggering sensitivity of which can be controlled by means of a potentiometer 3.1.

Hakkinen, Col. 10, lines 11-18, App. pg. 49. Based on the teachings of the specification, the word "tune" is interpreted to mean that the potentiometer is used to adjust the sensitivity of the triggering circuit, i.e., the breathing pressure that

"triggers" the release of oxygen to the user.

As noted above, Hakkinen describes a potentiometer that can alter the triggering sensitivity (i.e., the threshold breath pressure level) of the system. Thus the system of Hakkinen is capable of altering the threshold breath pressure level to a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal. If the potentiometer was not capable of adjusting the threshold breath pressure level to the appropriate lower level, certainly Mr. Hakkinen would have noted this in his declaration.

The Patent Owner also presented the declaration of Thomas A. Wenzel (the "Wenzel Declaration") to support their position that the potentiometer of Hakkinen was only used to tune and fix the sensitivity of the triggering circuit at the factory. With respect to the potentiometer, Mr. Wenzel states:

> Based on my review of the Hakkinen reference, the potentiometer disclosed in Hakkinen is used to tune the sensitivity of the triggering circuit during manufacturing based on product specifications and applications.

Wenzel Declaration, paragraph 19, App. pg. 109. Wenzel concedes that the potentiometer of Hakkinen can alter the triggering sensitivity (i.e., the threshold breath pressure level) of the system. Thus the system of Hakkinen is capable of

altering the threshold breath pressure level to a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal. In fact, Mr. Wenzel states that this is possible. Specifically, Mr. Wenzel states:

> In fact, I believe that it was against conventional wisdom to design an oxygen concentrator in which users are allowed to adjust the triggering sensitivity by using the rudimentary system disclosed in Hakkinen because the potentiometer shown in Hakkinen allows user to make free and continuous range of adjustments, which in turn could result in false firing, failure to detect breathes, and other product reliability issues.

Wenzel Declaration, paragraph 19, App. pg. 109. Mr. Wenzel states that using the potentiometer of Hakkinen to adjust the triggering sensitivity could result in "false firing." False firing by a conserver is due to the triggering sensitivity being set too low. For example, if the triggering sensitivity is set too low, the normal daytime activity of a person can cause the conserver to deliver oxygen at times when the user is not inhaling. Thus, Mr. Wenzel's statements confirm that the system of Hakkinen is capable of altering the threshold breath pressure level to a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal. Mr. Wenzel also concludes that:

> Hakinen shows a single potentiometer, which has a continuous resistance range that cannot be used to set pre-selected, discrete user-selectable levels. As such, even if the user could adjust the triggering sensitivity by tuning the potentiometer shown in Hakkinen, the system would not allow the user to set the triggering sensitivity at preselected discrete levels.

Wenzel Declaration, Paragraph 20, App. pg. 110. It is important to note that the claims do not require that the breath thresholds are pre-selected **discrete** user-selectable levels. The claims only require that the system provides a plurality of user selectable threshold pressure levels. A potentiometer that has a "continuous range of adjustments" has a plurality of user selectable threshold pressure levels. Adjusting the potentiometer changes the threshold pressure level of the triggering circuit. Once the user has completed the adjustment, the threshold pressure level is set at a user selected level. Whether the means for achieving the selection of the threshold pressure level is continuous or discrete is not a limitation of the claims. The claim merely requires that the system is capable of allowing the user to select a plurality of threshold pressure levels. The system described in Hakkinen is clearly capable of meeting this limitation.

The PTAB issued a Decision on Appeal (the "Decision") on July 1, 2014. The Decision affirmed that claims 1-3 are patentable over the cited art. In the Decision, the PTAB states:

> Regarding claim 1, Requester asserts that Hakkinen teaches the claimed user-selectable threshold pressure levels via the fact that Hakkinen contains a potentiometer that can control the triggering sensitivity of the device. Hakkinen Spec., col. 10:8-18. … We agree with Patent Owner that the mere presence of a potentiometer does not teach this claimed limitation. Hakkinen does not state anywhere that the potentiometer is a device intended to be used by the user/patient to adjust settings during operation. Accordingly, we are persuaded that it does not qualify as a "user selectable" device.

Decision, pg. 5, App. pg. 31.

> Without determining whether or not Hakkinen is limited to factory adjustment, the proper inquiry is whether the potentiometer is capable of user adjustment, and Hakkinen is silent regarding whether a user would use the potentiometer to adjust the settings as claimed. There simply is insufficient disclosure in Hakkinen regarding the function of the potentiometer to glean that it could operate to allow user selectability in the manner suggested by Requester to meet the claimed limitations.

Decision, pg. 6, App. pg. 32. As discussed above, with respect to the Hakkinen and Wenzel Declarations, the potentiometer disclosed in Hakkinen is clearly capable of operating to allow user selectabillity in the manner set forth in the claims. Thus the assumption of the PTAB that the potentiometer of Hakkinen is not capable of user adjustment is incorrect. The Decision of the PTAB is thereby flawed and does not properly support the assertion that the claims are patentable over the cited art.

From the above discussion, it is clear that the system of Hakkinen is capable

of altering the sensitivity of the triggering circuit. Since the trigger circuit is activated based on the value of the breathing pressure, changing the sensitivity of the triggering circuit is equivalent to changing the threshold breath pressure level. Thus, the system of Hakkinen is capable of being adjusted in the manner set forth in claim 1. Specifically, the system of Hakkinen is capable of having a plurality of user selectable threshold pressure levels, said threshold pressure levels comprising a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal. In fact, neither the Hakkinen Declaration nor the Wenzel Declaration make any kind of statement, or even suggest that, the potentiometer used to alter the sensitivity of the triggering circuit would not be capable of being set to a level such that the triggering circuit will trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal.

The PTAB's decision is based on the assumption that Hakkinen needs to explicitly teach that the potentiometer is capable of altering the threshold pressure levels in the manner set forth in claim 1 and is intended to be used by the user. This assumption is not correct. Whether the potentiometer was "intended" to be used to allow the user to select a lower threshold pressure level is immaterial to the analysis of whether the claims are obvious. The simple fact is that Hakkinen puts

no limits at all as to who or when the potentiometer in Hakkinen can be used. Regardless, the system of Hakkinen is capable of being adjusted to a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal. The system of Hakkinen teaches that a potentiometer can be used to make this adjustment. A person of ordinary skill, looking to solve the problem of being able to efficiently provide oxygen to a user during both active states and sleeping/inactive states, would understand that the system of Hakkinen is capable of being adjusted (by use of the potentiometer) to different threshold breath pressure levels. Adding a switch (or some other device) that allows a user to set the potentiometer to predefined positions (and thus adjust the threshold breath pressure level) of the system, would also be well within the skill of a person of ordinary skill in the art. Finally, as noted above, allowing the user to switch the threshold breath pressure level to a lower level will be the most efficient way of ensuring that the threshold breath pressure level is used during nocturnal sleep.

IV. Legal Analysis Of The Unpatentability Of Claims 1-3

The Federal Circuit has observed that determination of obviousness is a question of law. Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987) ("The Supreme Court, the regional Circuit Courts of Appeals, and this court have consistently treated the question as one of law.") (citing Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

Requestor respectfully requests the reversal of the PTAB's ruling that the Hakkinen reference does not teach a user selectable potentiometer on the grounds that it mistakenly applied the wrong legal standard in ascertaining the scope of the Hakkinen reference's teachings.

Claims 1-3 of Deane require that the "the system provides a plurality of user selectable threshold pressure levels." The PTAB held that "Hakkinen does not state anywhere that the potentiometer is a device intended to be used by the user/patient to adjust settings during operation. Accordingly, we are persuaded that it does not qualify as a 'user selectable' device." Decision on Appeal, pg. 5 (footnote omitted), App. pg. 31. We disagree with the PTAB decision.

The PTAB seems to agree in its Decision that Hakkinen teaches that *someone* sets a potentiometer. The PTAB's reading that it does not teach a user

setting the potentiometer is unduly narrow as a matter of law, particularly in light of the other art in the record that shows a need for user set potentiometers.

"The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Labs., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); see also Upsher-Smith Labs. v. Pamlab, LLC, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005) (reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component); Celeritas Tech. Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (the court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

Additionally, the Federal Circuit has observed that the PTAB's decision must be supported by "more than a mere scintilla" of evidence based on "examination of the record as a whole, taking into account evidence that both justifies and detracts from [the Office's] decision." In re Gartside, 203 F.3d 1305, 1312 (Fed. Cir. 2000) (citations omitted). Thus, Requestor respectfully submits that the PTAB, in finding "the proper inquiry is whether the potentiometer is capable of user adjustment" and finding that Hakkinen is silent as to whether the adjustment is factory or user based, overlooked the follow up legal question of whether Hakkinen would reasonably suggest to one of ordinary skill in the art a user selectable potentiometer. Concluding that Hakkinen is silent fails to consider the totality of the Hakkinen reference and the relevant knowledge of one of ordinary skill in the art at the time Hakkinen. Further, even if Hakkinen is silent as to user selectability, that does not compel the conclusion that one of ordinary skill would not find user selectability obvious.

Hakkinen recites "[t]hrough the same Finnish patent application of the assignee, an inhalation dispenser is also known incorporating an inspiration flow rate control for setting a desired magnitude, the inspiration flow rate advantageous for each individual patient." Hakkinen, Col. 2, lines 11–16, App. pg. 45 (emphasis added). Further, Hakkinen lists U.S. Patent No. 4,471,773 to Bunnell et al. as a

relevant reference. See "References Cited" on cover page of US 4,471,773, App. pg. 36. U.S. Patent No. 4,471,773 states:

> The gas pulses are produced by valve 16 which is cycled open and closed at a high frequency in response to signals from a microprocessor 17. … The microprocessor is programmable to produce the various signals desired by the user and may be any of a number of suitable devices, such as the Motorola 6801.

US 4,471,773, Col. 2, line 58 – Col. 3, line 5, App. pgs. 115-116 (emphasis added). Thus, user selectability of controls was well known in the art. Furthermore, U.S. Patent No. 4,267,832, in which Hakkinen is the sole named inventor, teaches:

> It is often advisable or necessary in connection with providing respiration by means of a respirator or like apparatus to be able to adjust the counter-pressure which is presented to the expiration of exhalation of the patient. In this connection, it is highly desirable to be able to adjust the extent of the counter-pressure presented during respiration in a stepless or continuous manner so that the most advantageous counter-pressure may be utilized **under the particular circumstances**.

US 4,267,832, col. 1, lines 13–21, Filed: Apr 17, 1979, App. pg. 126 (emphasis added). Thus, one of ordinary skill in the art would understand Hakkinen to teach customization of pressure parameters on a per patient and per circumstance basis. The use of a potentiometer in Hakkinen would naturally lead a person of ordinary skill in the art to consider allowing the user to adjust the settings of the system,

since such a device can be used to incorporate user selectablity in an oxygen concentrator, such as described in Deane. Thus, given that Hakkinen discloses a potentiometer, and a potentiometer can be used to adjust the operating parameters by a person, for purposes of an obviousness analysis, one should conclude that Hakkinen discloses or suggests a user selected potentiometer.

Furthermore, the APA (and Aylsworth) teach that there is need for a lower breath pressure threshold in order to accurately detect breathing when the patient is asleep. It is obvious that the user will be aware that they are going to go to bed to sleep. Allowing the user to switch the threshold breath pressure level to a lower level will be the most efficient way of ensuring that the threshold breath pressure level is used during nocturnal sleep.

A person of ordinary skill, looking to solve the problem of being able to efficiently provide oxygen to a user during both active states and sleeping/inactive states, would understand that the system of Hakkinen is capable of being adjusted (by use of the potentiometer) to different threshold breath pressure levels. Modifying the potentiometer to allow user selectability of the threshold pressure level by adding a switch (or some other device) that allows a user to set the potentiometer to predefined positions (and thus adjust the threshold breath pressure

level) of the system, would be well within the skill of a person of ordinary skill in the art.

The Supreme Court in KSR International Co. v. Teleflex Inc., cautions against the type of analysis used by the PTAB to affirm the patentability of claims 1-3 of Deane. 550 U.S. 398, 82USPQ2d 1385 (2007). Specifically, the Supreme Court warns against the following pitfalls: (1) "courts and patent examiners should look only to the problem the patentee was trying to solve" (Id. at 420, 82 USPQ2d at 1397); (2) by assuming "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem" (Id.); (3) by concluding "that a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try'" (Id. at 421, USPQ2d at 1397); and (4) by overemphasizing "the risk of courts and patent examiners falling prey to hindsight bias" and as a result applying "[r]igid preventative rules that deny factfinders recourse to common sense" (Id.). The PTAB has fallen into the traps that the Supreme Court specifically warned against. Specifically, the PTAB finding that the references fail to teach a "user selectable" feature is denying the common sense solution that would be obvious to any person of ordinary skill in the art.

The Supreme Court, in *KSR*, states that:

> The obviousness analysis cannot be confined by . . . overemphasis on the importance of published articles and the explicit content of issued patents. . . . . In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends.

KSR, 550 U.S. at 419, 82 USPQ2d at 1396.

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

Id. at 417, 82 USPQ2d at 1396. The PTAB fails to consider the obvious techniques and modifications that a person of ordinary skill in the art would recognize to improve the system of Hakkinen. As discussed above, the system of Hakkinen includes all of the components necessary to implement the user selectability features of claims 1-3 of Deane. Given that the problem of supplying oxygen to a user while asleep or inactive was a well-known problem at the time of the invention, the modification of Hakkinen by allowing a user to be able to alter

the sensitivity of the potentiometer, in order to solve this problem is an obvious solution that is well within the skill of a person of ordinary skill in the art.

In fact, the solution is so obvious, that Deane does not even feel the need to describe what equipment is needed to implement the user selectability of the threshold pressure level. With respect to the user selectability of the threshold pressure level, Deane states:

> Normal Activity Mode and Sleep Mode Threshold Pressure Settings
>
> In one embodiment, as shown in FIG. 5, the system has settings for switching between a 'day' or 'normal activity' mode 502 and a 'night' or 'sleep' mode 504. A lower threshold pressure level or higher sensitivity is preferably used when the patient is sleeping. The bolus is preferably triggered at an earlier time in the inspiratory cycle, allowing for full bolus delivery before the first half of the cycle. Several implementations of this embodiment are possible. The patient may simply be given a user input to the controller, allowing for several different threshold pressure settings or sensitivities, user selectable, to be entered into the controller. The patient may choose a value to be used during normal activity in the day, and change to a lower value to be used at night when the patient is sleeping. Alternatively, either a "day" or "night" mode may be selected, with the sensitivities, A and B programmed into the controller by the patient's caregiver, or loaded at the factory. Although a lower threshold value is more susceptible to false triggers, a sleeping patient is typically quite still and less prone to generate pressure noise in the cannula, which may lead to false triggers. Thus, a higher nighttime sensitivity can be effective, especially if low electrical signal noise can be achieved.

Deane, Col. 7, lines 5-28, App. pg. 15. It should be noted that Deane, when explaining the implementation of the "day" and "night" modes only teaches that "a user input to the controller" may be added to the system. Deane does not describe what happens when a user input of "day" or "night" mode is made. How does the controller change the sensitivity of the pressure sensor? Does the controller even need to change the sensitivity of the pressure sensor? What kinds of pressure sensors are present? If the implementation is a software implementation, is there some sort of automatic switching of the sensitivity of the sensor (e.g., by automatically adjusting a potentiometer coupled to the sensor)? The fact that Deane deems these details as unnecessary for enablement of the invention indicates that **a person of ordinary skill in the art at the time of the invention** is well aware of many techniques to allow a user to alter the sensitivity of the pressure sensors. Thus, Deane teaches that a person of ordinary skill in the art, presented with the concept of the need to alter the threshold pressure level based on the activity level of the user, would not need any further teachings to implement the concept.

The prior art reference (or references when combined) need not teach or suggest all the claim limitations. The "mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness."

Dann v. Johnston, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976). The gap between the prior art and the claimed invention may not be "so great as to render the [claim] nonobvious to one reasonably skilled in the art."

In *KSR* the Supreme Court set forth various rationales that may support a conclusion of obviousness. These rationales include:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have

led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Many of these rationales can be used to support the why modifying Hakkinen in view of the APA (or Ayslworth) renders the claims obvious.

For example, claims 1-3 of Hakkinen are obvious in view of the cited art under the rationale that simple substitution of one known element for another can be used to obtain predictable results. In this case Hakkinen teaches a device that includes all of the components of the device claimed in claim 1. Hakkinen, however, does not explicitly teach the need to set the threshold breath pressure level to a lower level when the user is asleep or in a state of inactivity and that the "the system provides a plurality of user selectable threshold pressure levels." As noted previously, the APA (or Alysworth) teach the need for different threshold pressure levels. Furthermore Hakkinen teaches that a potentiometer can be used to alter the threshold pressure level. The PTAB is of the opinion, however, that the potentiometer of Hakkinen is not a "user selectable" device. While we disagree with this interpretation of the prior art, even if the PTAB's opinion is deemed to be correct, it would be a simple matter of substituting a user adjustable potentiometer for the potentiometer of Hakkinen to allow a user to make the necessary adjustments. Since this could be done with little or no modification of the actual

potentiometer, there would be a reasonable expectation of success. Under this rationale, the claims are unpatentable over Hakkinen in view of the APA (or Aylsworth).

Another rationale that may be used to justify modifying the potentiometer to be more user accessible is that the inventors simply applied a known technique to a known device ready for improvement to yield predictable results. Under this rationale, a "base" device is found in the prior art upon which the claimed invention can be seen as an improvement. The Hakkinen system would be considered the "base" device as it contains all of the claimed components of the system set forth in claims 1-3. The claimed improvement would be adding a plurality of user selectable threshold pressure levels, said threshold pressure levels comprising a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal. The APA (or Alysworth) teach the need to have multiple threshold pressure levels to accommodate the user's activity level. Hakkinen teach that user selectability of controls was well known in the art. The known technique (user selectability of conserver operation) can be applied to the system of Hakkinen. The addition of user selectablity of controls to the system of Hakkinen would have the predicable result of allowing the user to adjust the sensitivity to correspond to

the user's activity level. Thus, under this rationale, the claims are unpatentable over Hakkinen in view of the APA (or Aylsworth).

"A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR, 550 U.S. at 421, 82 USPQ2d at 1397. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. at 420, 82 USPQ2d at 1397. One may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. at 418, 82 USPQ2d at 1396.

Thus, for the hypothetical person of ordinary skill in the art, when confronted with the problem of ensuring that the breath pressure threshold is set to the appropriate sensitivity when the patient is sleeping, modifying the device of Hakkinen with a user selectable external device that allows the user to adjust the sensitivity is an obvious modification to a known device using a known technique. The motivation for this modification is provided by the APA which teaches that the breath pressure threshold level should be lowered to ensure that the therapeutic gas is delivered to the patient when the patient is sleeping.

CONCLUSION/STATEMENT OF RELIEF SOUGHT

As has been shown above, claims 1-3 of Deane are non-patentable over Hakkinen in view of the APA (or Aylsworth). The PATB clearly erred when they affirmed the Examiner's decision to allow claims 1-3 in view of the cited art. We respectfully request that the court reverse the ruing of the PATB by confirming that claims 1-3 are directed to unpatentable subject matter.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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December 19, 2014
(Date)

COPY OF PATENT (DEANE)

US007841343B2

(12) **United States Patent**
Deane et al.

(10) **Patent No.: US 7,841,343 B2**
(45) **Date of Patent: Nov. 30, 2010**

(54) **SYSTEMS AND METHODS FOR DELIVERING THERAPEUTIC GAS TO PATIENTS**

(75) Inventors: **Geoffrey Frank Deane**, Goleta, CA (US); **Brenton Alan Taylor**, Kenwood, CA (US)

(73) Assignee: **Inogen, Inc.**, Goleta, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1122 days.

(21) Appl. No.: **11/147,409**

(22) Filed: **Jun. 6, 2005**

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Related U.S. Application Data

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(51) **Int. Cl.**
A61M 11/00 (2006.01)

(52) **U.S. Cl.** **128/204.23**; 128/204.18

(58) **Field of Classification Search** 128/204.23, 128/204.18; 600/538
See application file for complete search history.

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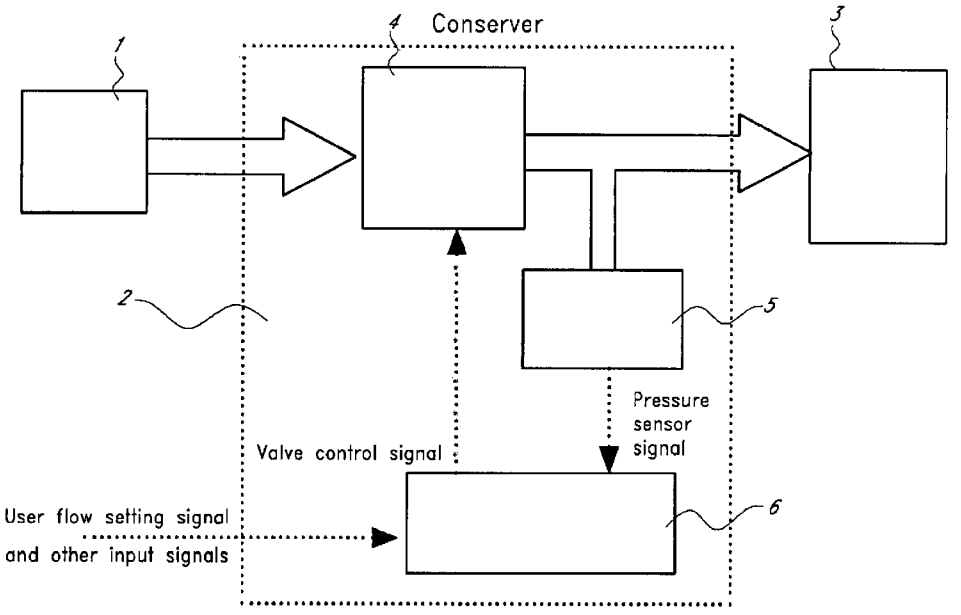
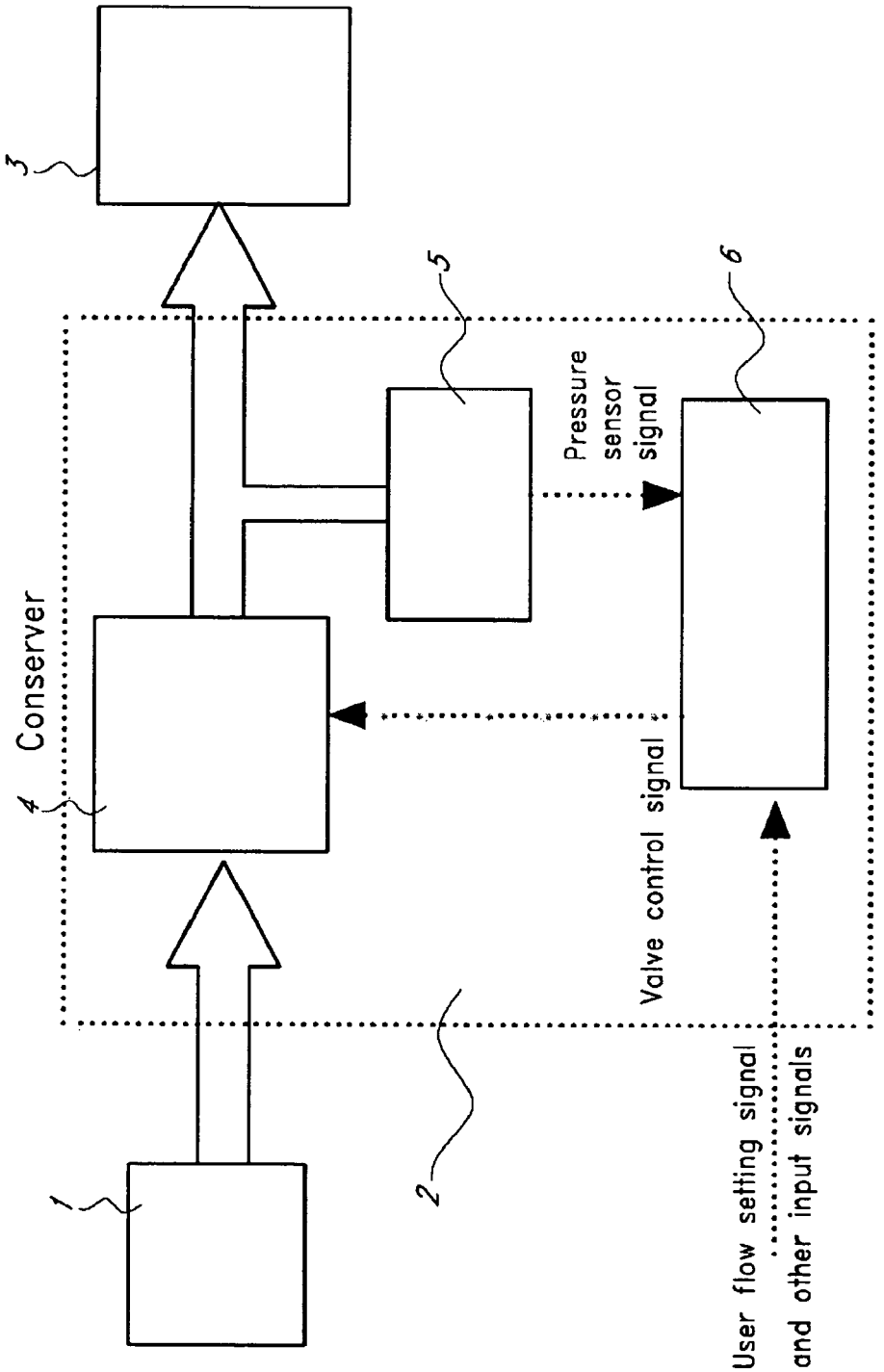
(57) **ABSTRACT**

A system for delivering therapeutic breathing gas to patients is provided to deliver a variable bolus volume in response to the patient's breathing pattern. The system includes a gas source, a conserver between the gas source and the patient, a sensor which detects breaths by the patient and a controller which receives signals from the sensor and triggers delivery of gas boluses in accordance with predefined triggering parameters, with the controller determining the time elapsed since the last bolus was triggered and altering the triggering parameters as a function of the elapsed time.

12 Claims, 10 Drawing Sheets

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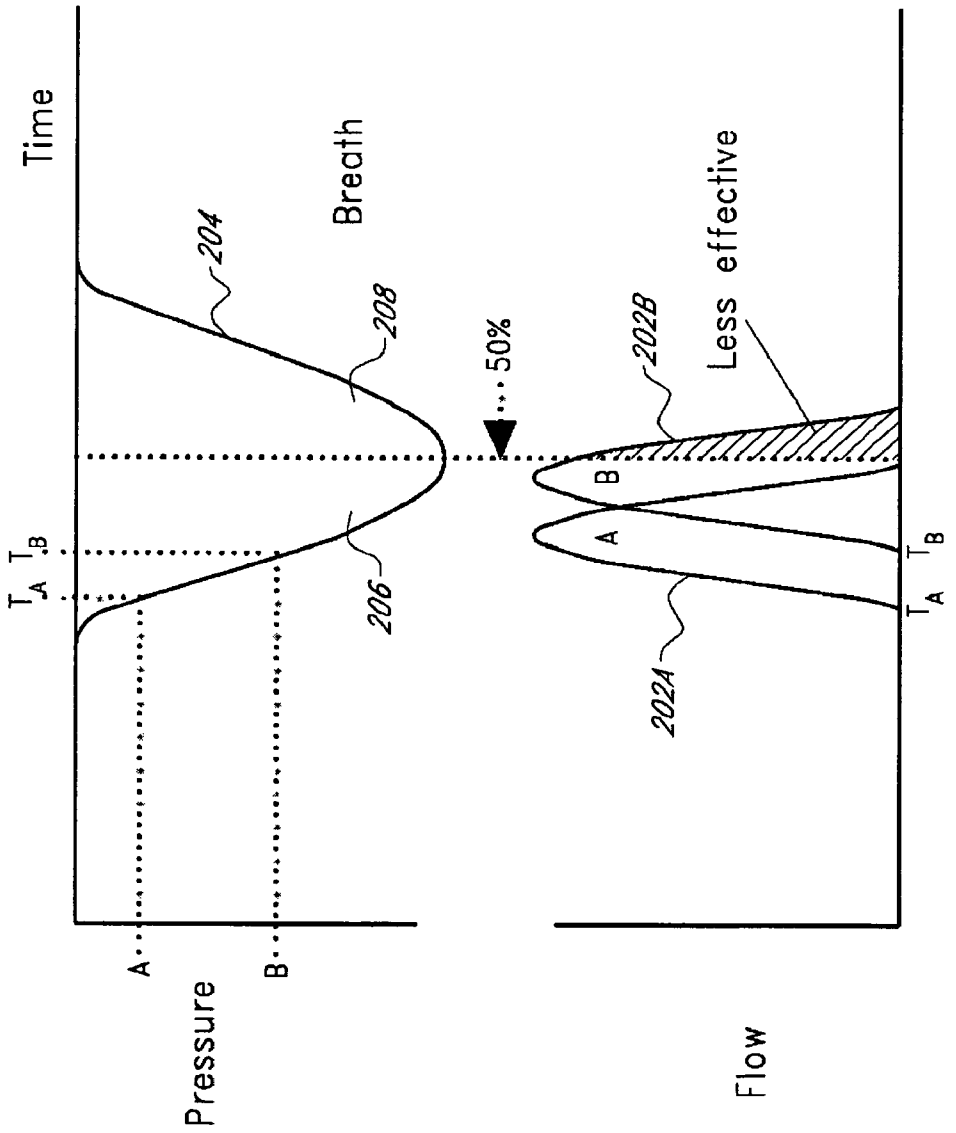
5
6
Pressure sensor signal
Conserver
4
Valve control signal
2
1
User flow setting signal and other input signals

FIG. 1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208
206
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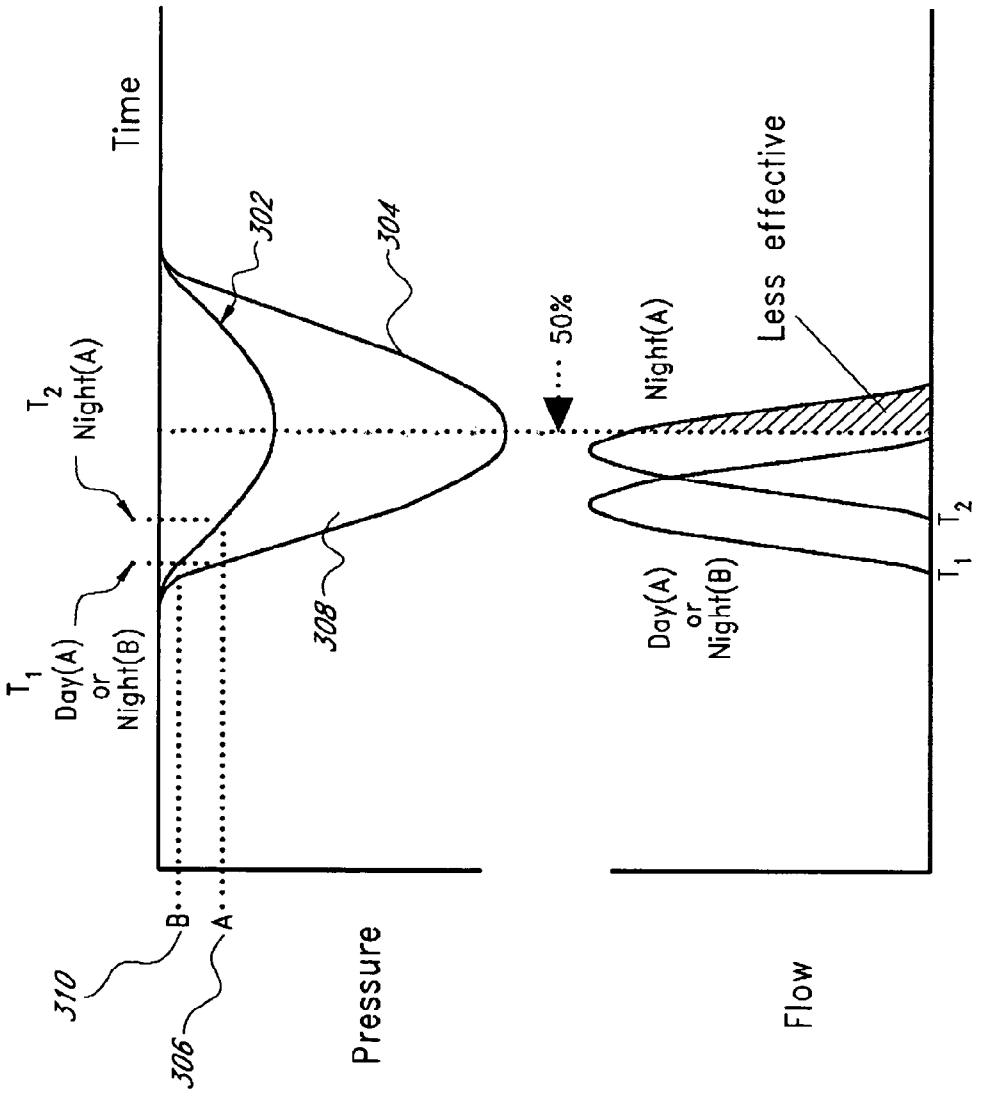
202B
Less effective
202A
A
B
T_A T_B
Pressure
Flow

FIG. 2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302
304
50%
Night(A)
Less effective
T2
Night(A)
T1
Day(A)
or
Night(B)
308
Day(A)
or
Night(B)
T1 T2
B
A
310
306
Pressure
Flow

FIG. 3

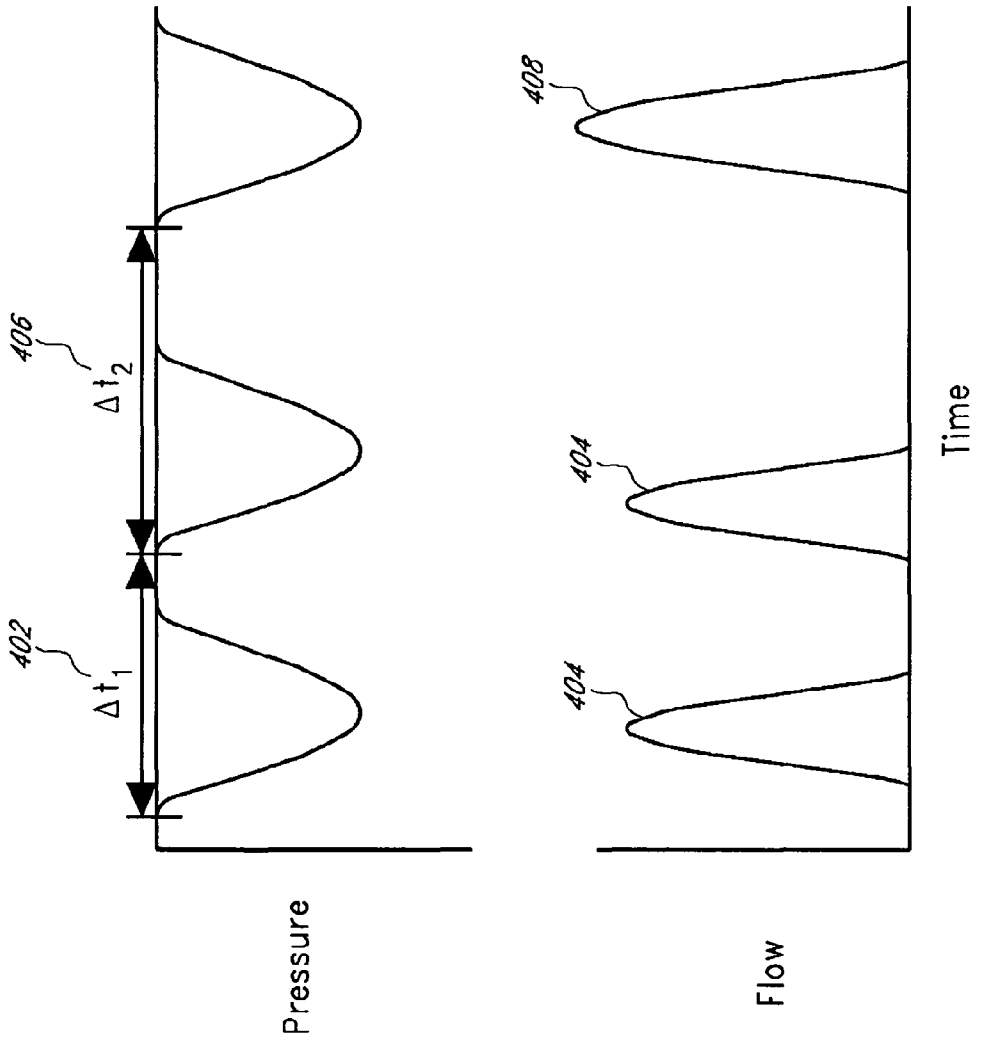

FIG. 4

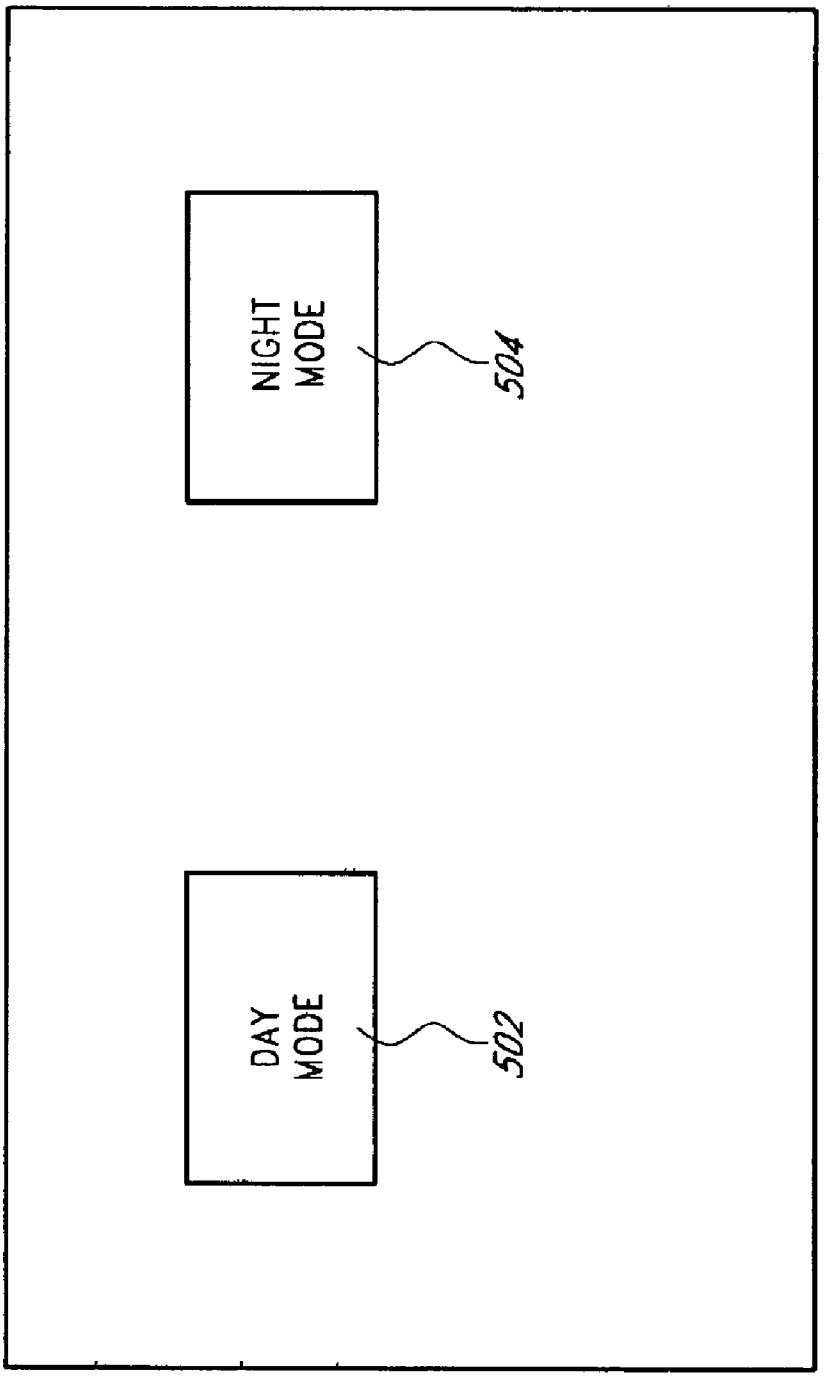

FIG. 5

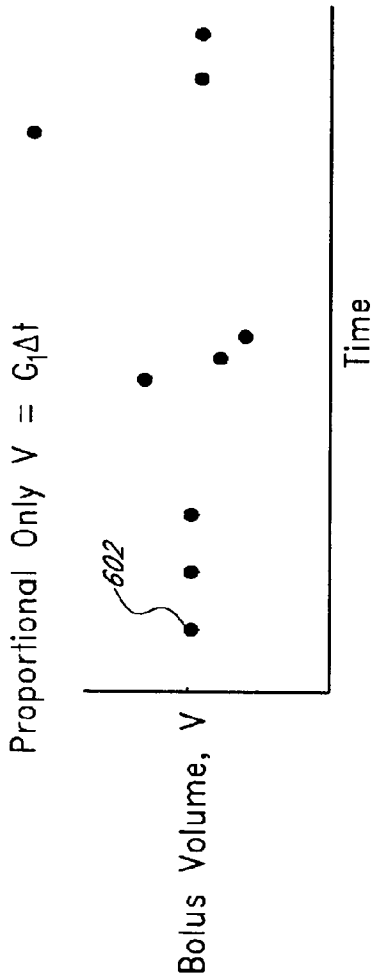
Proportional Only V = G1Δt
602
Bolus Volume, V
Time

FIG. 6A

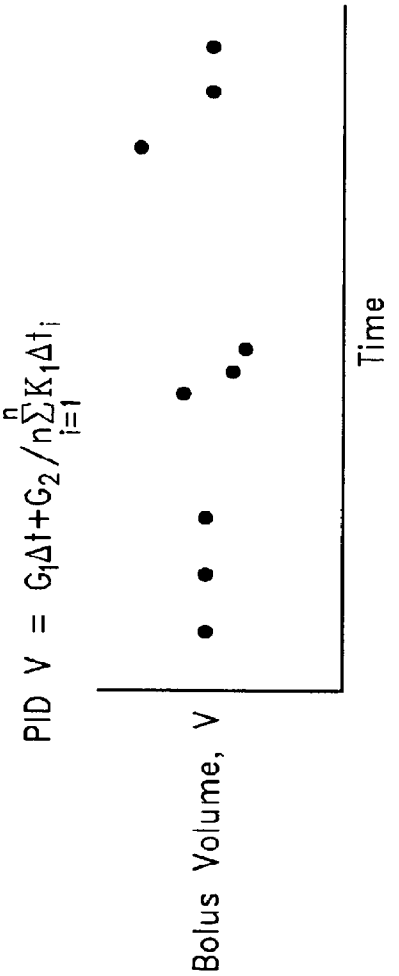
PID V = G1Δt+G2/n∑i=1n K1Δti
Bolus Volume, V
Time

FIG. 6B

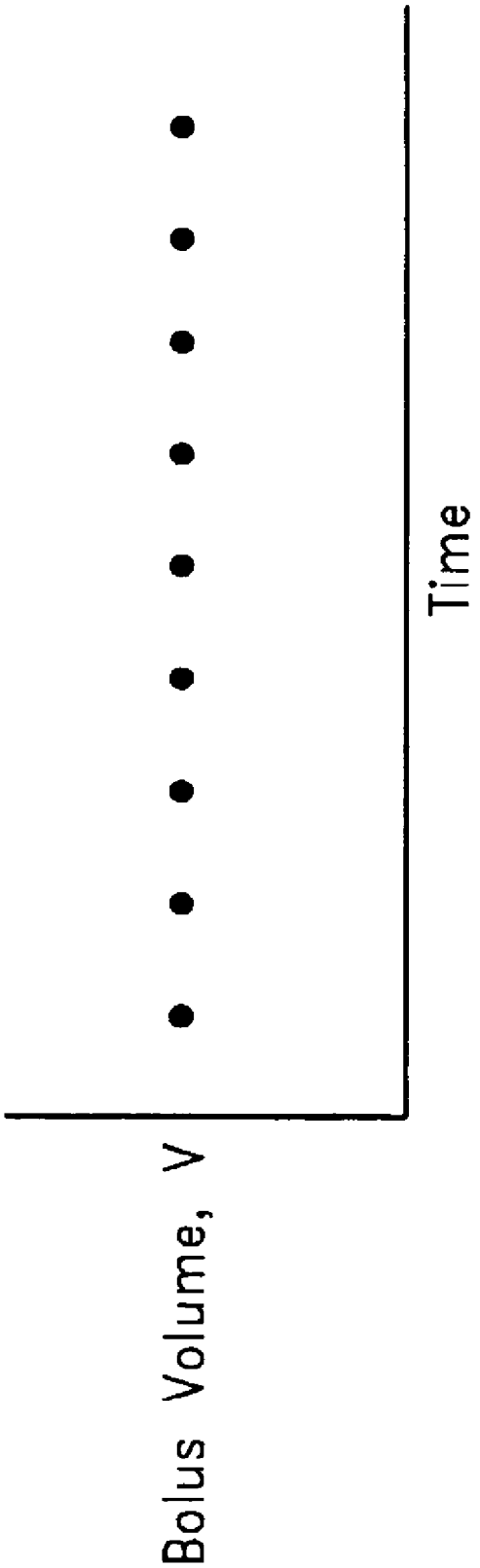

FIG. 7

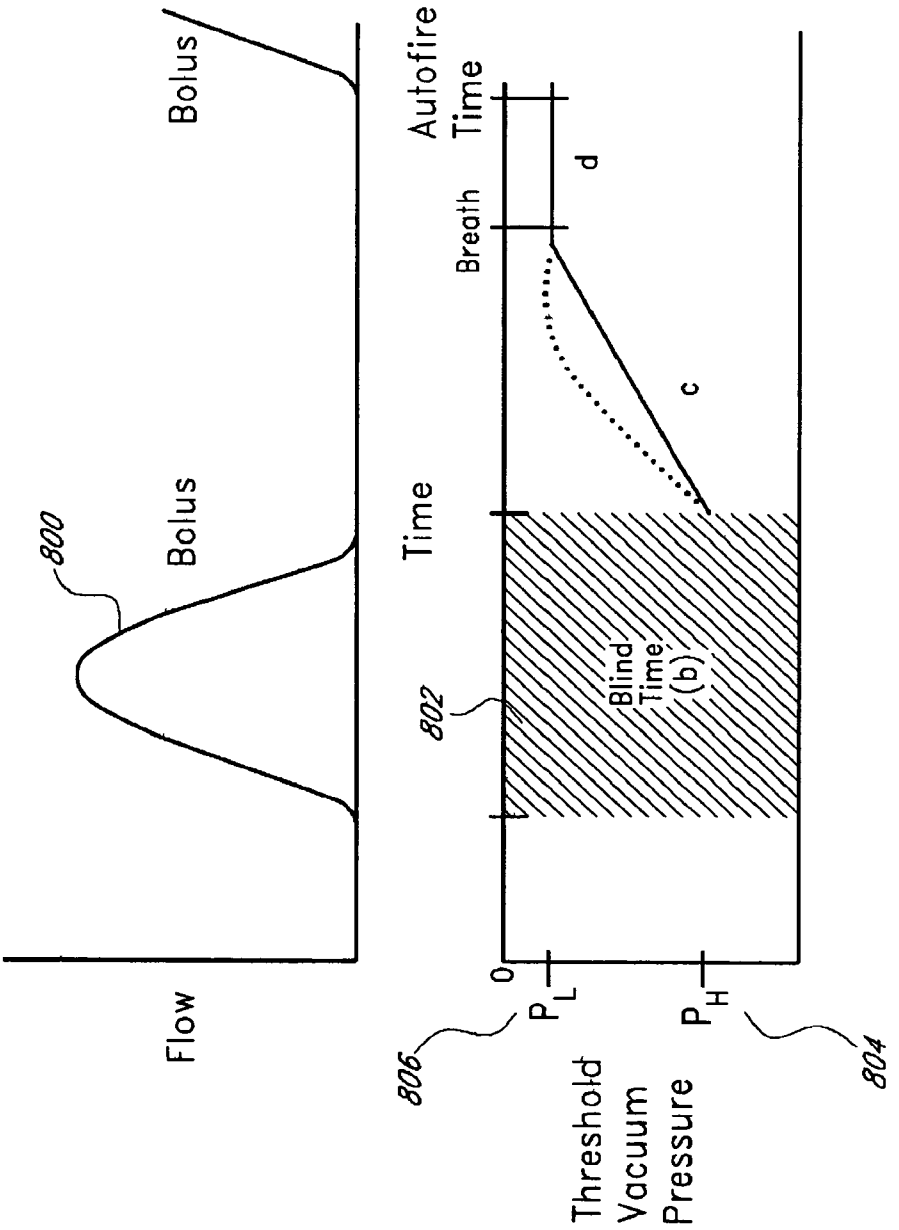
Bolus
Bolus
800
Flow
Autofire
Time
Breath
d
c
Time
802
Blind
Time
(b)
0
P_L
P_H
806
804
Threshold
Vacuum
Pressure

FIG. 8

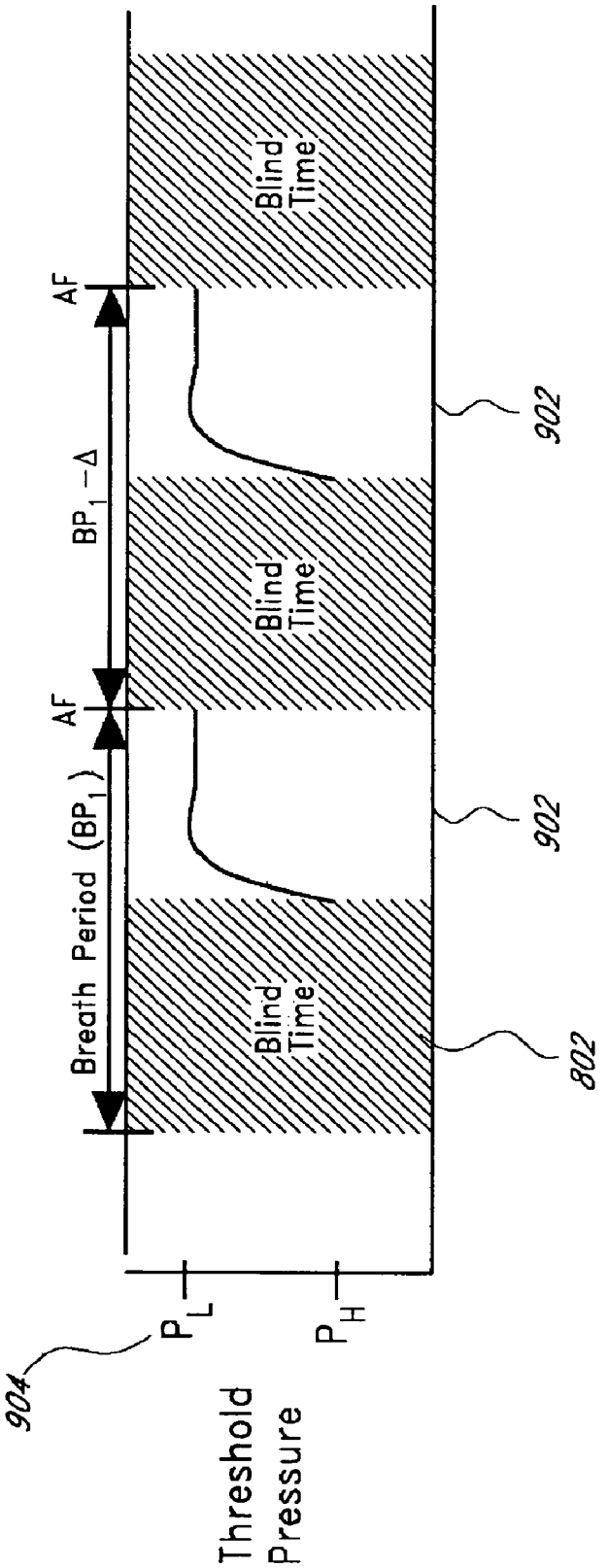
Blind Time
AF
$BP_1 - \Delta$
Blind Time
AF
Breath Period (BP_1)
Blind Time
902
902
802
904
P_L
P_H
Threshold Pressure

FIG. 9

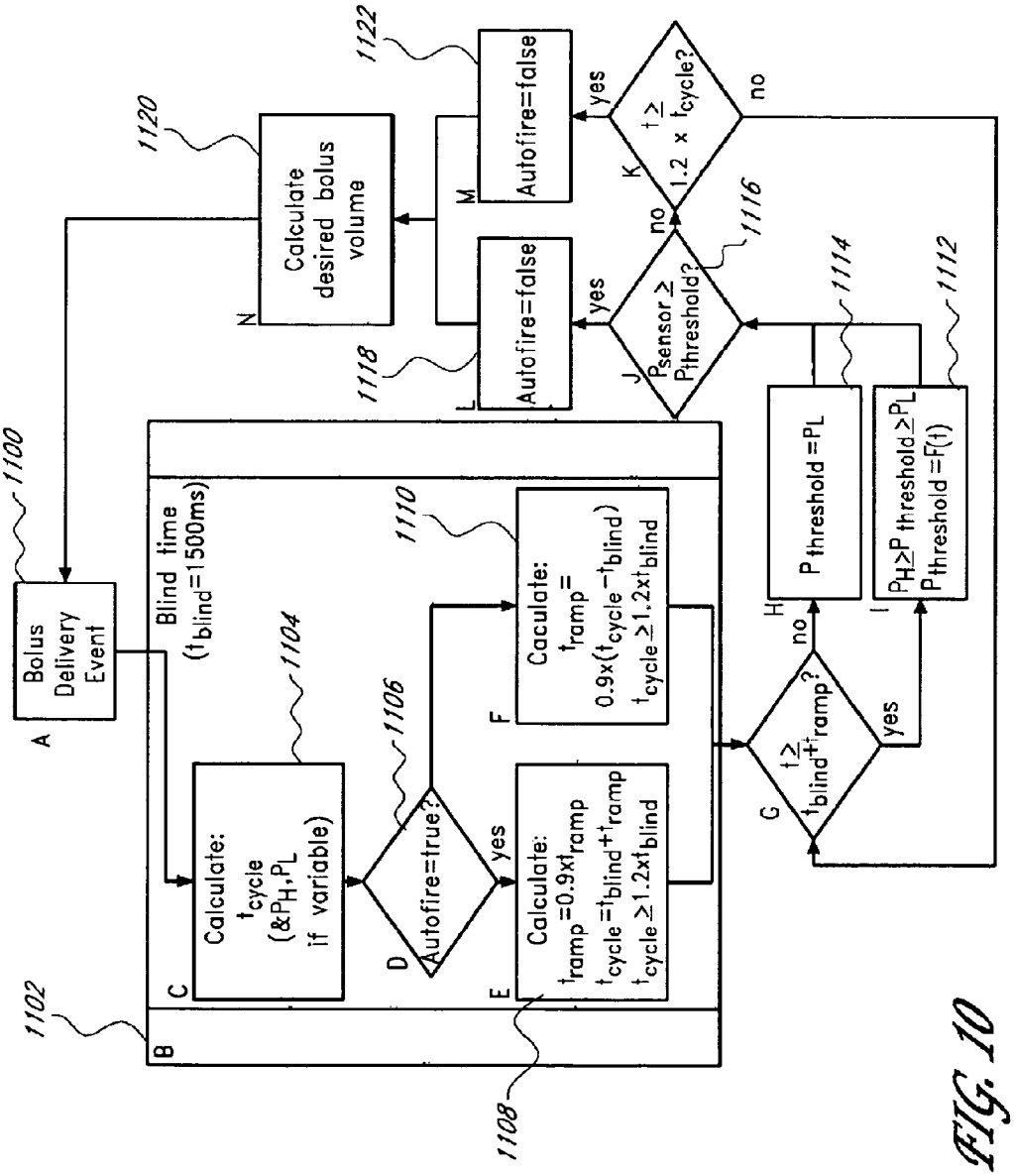
1100
Bolus Delivery Event
A
1102
Blind time (t_{blind}=1500ms)
B
1104
C
Calculate: t_{cycle} (&P_H,P_L if variable)
1106
D
Autofire=true?
yes
1108
E
Calculate: t_{ramp}=0.9xt_{ramp} t_{cycle}=t_{blind}+t_{ramp} t_{cycle}≥1.2xt_{blind}
1110
F
Caculate: t_{ramp}= 0.9x(t_{cycle}-t_{blind}) t_{cycle}≥1.2xt_{blind}
G
$t \geq t_{blind}+t_{ramp}$?
no
yes
H
P threshold =P_L
I
$P_H \geq P_L$ P threshold =F(t)
1112
1114
1116
J
$P_{sensor} \geq P_{threshold}$?
no
yes
K
$t \geq 1.2 \times t_{cycle}$?
no
yes
1118
L
Autofire=false
M
1120
N
Calculate desired bolus volume
1122
Autofire=false

FIG. 10

SYSTEMS AND METHODS FOR DELIVERING THERAPEUTIC GAS TO PATIENTS

RELATED APPLICATIONS

This Application claims the benefit of U.S. Provisional Patent Application Ser. No. 60/577,088, filed Jun. 4, 2004, which is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to systems and methods for delivering therapeutic gas to patients, and in particular, relates to such systems and methods in which the gas delivery is tailored to the patient's breathing pattern.

2. Description of the Related Art

The application of oxygen concentrators for therapeutic use is known, and many variants of such devices exist. A particularly useful class of oxygen concentrators is designed to be portable, allowing users to move about and to travel for extended periods of time without the need to carry a supply of stored oxygen. Such portable concentrators must be small and light to be effective. Oxygen concentrators in general are implicitly limited in terms of the rate at which they can deliver oxygen to the patient, but benefit because they are only duration-limited by their access to electric power. To make the portable concentrators small and light, the rate at which oxygen is concentrated by the device is further restricted. However, use of a device called a conserver, which is placed in the product line between the concentrator and the patient, mitigates this limitation.

The conserver, many designs of which are known in the art, senses a patient's breath demand, and responds by delivering a volume of oxygen-rich gas (known as a bolus) to the patient. This bolus, which is often significantly less than the total volume of a typical inhalation, is entrained in the breath's air intake, and mixes with the air, eventually reaching the lungs, esophagus, and respiratory cavities (nose and mouth). Approximately half of an inspiration enters the lungs, where oxygen is adsorbed. Elevated oxygen concentration in this volume result in greater transfer of the gas to the blood, which enhances the health of the patient. Because the lungs can only make use of oxygen in the volume that reaches them, it is important that the bolus be delivered during the portion of an inhalation that actually reaches the lungs. As this is typically the first fifty percent of a breath, the bolus should be delivered quickly, requiring that the bolus delivery start as rapidly as possible after the start of the patient's breathe. Quick delivery of the bolus allows smaller boluses to be delivered while still satisfying the patient's need for oxygen. Thus, conservers that deliver an effective therapeutic amount of oxygen in relatively small, short bursts, constitute a more efficient use of the concentrated product gas. This allows for the design of small, lightweight concentrators that are equally effective as the large continuous flow gas supplies.

Although one of the primary motivations behind small concentrators is to allow patient freedom and mobility, the cost of these devices makes it advantageous if the concentrator is a single solution, used 24 hours a day, for all of a patient's oxygen needs. In order to be so employed, it is desirable to maximize the concentrator's efficacy while a patient is sleeping. However, there is concern in the respiratory care field that conserver-based delivery of oxygen is not as effective as continuous flow gas supplies at maintaining patient blood oxygen saturation levels during sleep.

One cause for this nighttime desaturation concern surrounds the conserver's sensitivity, or the inhalation vacuum pressure (typically sensed through a nasal cannula) that

results in a bolus delivery. In order to reduce false triggers (bolus delivery when no breath has occurred), breath detection, which is accomplished by measuring inhalation vacuum pressure typically through a nasal cannula, is set to a level corresponding to normal daytime breathing and activity patterns. If the pressure at which the conserver triggers a bolus is too low, normal activity may cause false firing, which can be disconcerting to patients and is ineffective oxygen therapy as much of this oxygen does not reach the lungs. However if the trigger pressure is too high, the conserver does not recognize a breath until a significant portion of it has already been inspired, which reduces the efficacy of the delivered bolus. Thus, it is desirable to have the conserver's breath sensitivity be as high as possible such that bolus delivery speed is accelerated, so long as this sensitivity remains low enough to avoid activity-induced false firing.

In addition, conserving devices typically deliver a predetermined volume of gas in response to patient breath demand. During sleep, the normal daytime trigger levels may be too high, and the associated bolus volumes may not be adequate to maintain required blood oxygen saturation levels. Moreover, during sleep, some patients are shallow and/or irregular breathers, such that nighttime breathing for these patients may not generate enough vacuum pressure to trigger bolus delivery. In some cases, due to irregular breathing patterns, the conserver may not detect every breath, resulting in breath skipping. In either of these cases, a bolus may not be triggered often enough to deliver enough oxygen to the patient over time. Many conservers are equipped with a breath detection or apnea alarm that notifies the user when no breath has been detected for some period. However, the alarm can awaken the sleeping patient, which makes use of the conserver not feasible.

Since most therapeutic gas systems deliver gas and sense patient breathing through a nasal cannula, patients who breathe through their mouths at night may never trigger bolus delivery. It is known within the respiratory care field that while patients are breathing through their mouths, they are entraining oxygen rich gas stored in the nasal passages with each inhalation. As such, large air supply systems simply deliver continuous flow to the nasal passages. However, continuous flow oxygen delivery, when not inhaled through the nose, may result in a cloud of oxygen-enriched gas around the face with oral inhalation entraining only some of this gas. As a result, the rate of oxygen delivery in these continuous flow oxygen systems often have to be increased during sleep to compensate for these inefficiencies in delivery.

Thus, it is apparent that new approaches to conserver-based delivery for sleep mode operation are desired in order to provide patients with the opportunity to use the small air concentrators 24 hours a day.

SUMMARY OF THE INVENTION

In one aspect, the preferred embodiments of the present invention provide an improved system for delivering therapeutic breathing gas, typically but not limited to oxygen from a concentrator, to a patient. The system generally includes a gas source, a conserver between the gas source and the patient, a sensor for detecting patient breath events and measuring the parameters of the breath events, and a processor and control elements for acquiring signals from the sensor and controlling the delivery of gas to the patient. Preferably, the gas is oxygen and the gas source is an oxygen concentrator. In one embodiment, the system supports at least one mode of operation such that the level of breath pressure detected by the sensor, which causes the processor and control elements to deliver a volume of gas to the patient, may be set to several different levels. In one implementation, the levels are user selectable. In another implementation, the different levels

comprise two user selectable levels, representing a night mode and a day mode, wherein the actual values of each level is determined by the patient's caregiver.

In another embodiment, the system supports at least one mode of operation such that the level of sensitivity, or the minimum inhalation vacuum pressure required for the conserver to register a breath detection and to initiate bolus delivery in response, may be set to several different levels. In one implementation, the conserver may be adjusted to operate over a range of sensitivity levels. The sensitivity levels may be pre-set discrete values that are pre-selected. In another implementation, two operating modes are user selectable. The two operating modes can represent a night or sleep mode and a day or activity mode. The sensitivity of the conserver may be different in each mode to allow for different activity levels and breathing characteristics. The sensitivity level for each of the above modes may be either accessed through a simple user interface such that the patient may manually adjust the sensitivity. Alternatively, access to the sensitivity settings may be more difficult, designed such that the actual values are selected by the patient's caregiver.

In yet another embodiment, the system supports at least one mode of operation where a fixed volume of gas is automatically delivered to the patient at a fixed rate ("auto-firing mode"). In one implementation of this embodiment, a conserving device delivers boluses at a fixed bolus volume and a fixed rate such that the product of volume times the rate closely matches a desired volume flow delivery rate. In another implementation of this embodiment, the desired volume flow delivery rate matches the capacity of an oxygen concentrator to produce oxygen.

In yet another embodiment, the system supports at least one mode of operation such that the sensitivity varies in response to breathing characteristics. In this embodiment, the conserver controller may vary the threshold pressure signal at which breath detection occurs in response to other system parameters. In one implementation, the system supports at least one mode of operation such that:

- the processor determines the average "breath period", or average time between successive bolus delivery events or breath detection events;
- the processor and control elements ignore any vacuum pressure signals, for a first fraction of the breath period termed the "blind time" (the time required to deliver a bolus resulting from the first inhalation detection event may be a subset of this period);
- the processor and control elements vary the breath detection threshold pressure signal at which gas delivery will occur from a high level to a low level during a second fraction of the breath period; and
- the processor and control elements hold the breath pressure level at the low level until a breath occurs.

The rate at which the breath detection threshold pressure signal decreased during the second fraction of the breath period may be linear. Alternatively, the rate of increase may follow an exponential function or other suitable functions.

In yet another embodiment, the system operates such that if no breath occurs after a preset time period, the system automatically delivers or auto-fires a volume of gas to the patient. The preset time period is referred to as "auto-fire time". In one implementation, this auto-fire bolus volume may be fixed, dependent only on user flow setting. In another implementation, this auto-fired bolus volume may vary in proportion to the elapsed time since the last bolus volume delivery was initiated, or in a manner reflecting a proportional-integral-derivative (PID) control method in response to a bolus delivery rate. In yet another implementation, the threshold pressure may continue to decrease until either a breath is detected or a bolus is automatically fired. In this implementation, the threshold pressure may linearly or asymptotically approach zero, or a value less than signal noise on the pressure sensor, resulting in an automatic bolus firing. In the event of automatically delivering a breath to the patient, the processor sets a shorter breath period than the previous breath period for use in determining the auto-fire time for the next breath cycle. When combined with other embodiments, this shorter breath period may also result in changes in threshold pressure ramp rates or other characteristics based on time. In the event that the conserver auto-fires repeatedly, successively reducing the breath period used in controlling the sensitivity and/or other parameters for each subsequent breath, the breath period approaches some minimum value. This value is preferably longer than the blind time, so as to allow some period during each breath period where a breath may be detected. The rate at which the breath period is reduced may be linear, exponential, or may asymptotically approach this minimum value.

In yet another embodiment, the system supports at least one mode of operation such that the system auto-fires after some period of time if no breath are detected. In the event of auto-firing to the patient, the processor reduces the threshold pressure for breath detection during the subsequent delivery cycle. In another implementation, the processor reduces both the threshold pressure and the breath period simultaneously, with each varying as described in above embodiments.

In yet another embodiment, the system supports at least one mode of operation such that the conserver controller increases or decreases the threshold pressure in response to regularity of breathing. In one implementation, the conserver controller measures the average breath period and breath period variance over a multiplicity of breaths, and incorporates the regularity of breathing patterns in determining the auto-fire time. In this way, a conserver used by a patient who is exhibiting irregular but detectable breathing patterns will pause for a longer period of time auto-firing; a conserver used by a patient who is breathing regularly until a sudden lapse in detected breath occurs will receive an auto-fired bolus more quickly.

In another aspect, the preferred embodiments of the present invention provide a method of delivering a series of boluses of gas to a patient. The method comprises triggering the delivery of each of a plurality of boluses in accordance with triggering parameters, determining the elapsed time since the last bolus was delivered, and altering the triggering parameters as a function of the elapsed time. In one embodiment, altering the triggering parameters comprises disabling triggering for a blind time. In another embodiment, altering the triggering parameters comprises altering the threshold for triggering. Preferably, altering the threshold for triggering comprises altering a threshold pressure, which can include decreasing the threshold pressure linearly over time or decreasing the threshold pressure asymptotically over a period of time. In certain preferred embodiments, the triggering parameters are a function of the triggering parameters of one or more boluses delivered prior to triggering the delivery. In one implementation, altering the triggering parameters comprises triggering an auto-fire delivery of a bolus when said elapsed time is greater than or equal to a predetermined time. Preferably, the predetermined time is decreased when auto-fire delivery is triggered. In some embodiments, the method further comprises reducing a blind time when auto-fire delivery is triggered.

In yet another aspect, the preferred embodiments of the present invention provide an apparatus for delivering a series of boluses of gas to a patient. The apparatus comprises a gas source, a conserver between the gas source and the patient, a sensor which detects breaths by the patient, and a controller which receives signals from the sensor and triggers a delivery of gas boluses in accordance with predefined triggering parameters. Preferably, the controller determines the time

elapsed since the last bolus was triggered, and altering the triggering parameters as a function of the elapsed time. In one embodiment, the triggering parameters comprise a blind period during which the triggering delivery of gas boluses is disabled. In another embodiment, the triggering parameters comprise a threshold inspiratory pressure of the patient. In yet another embodiment, the controller triggers an auto-fire bolus when the elapsed time is greater than a predetermined time. In certain modes, each of the triggering parameters is a function of the triggering parameters of one or more boluses previously delivered.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram of a therapeutic gas delivery system according to one preferred embodiment of the present invention;

FIG. **2** is a graphic illustration showing the relationship between the timing of a bolus delivery during an inspiratory cycle and the efficacy of the gas delivered;

FIG. **3** is a graphic illustration showing the pressure profiles of exemplary inspiratory cycles of a patient's breath during normal activity and during sleep;

FIG. **4** illustrates a mode of operation of the system of FIG. **1** in which the bolus volume delivered is a function of the elapsed time between successive breaths;

FIG. **5** schematically illustrates the system as having a day mode and a night mode of operation;

FIGS. **6**A and **6**B illustrate different embodiments of the operational mode of FIG. **4**;

FIG. **7** illustrates an auto-fire mode of operations of the system of FIG. **1**;

FIG. **8** illustrates an adaptive mode of operations of the system of FIG. **1**;

FIG. **9** illustrates another embodiment of the adaptive mode of FIG. **7**; and

FIG. **10** is a flow chart illustrating a method of delivering a therapeutic gas to patients according to one preferred embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

One preferred embodiment of a therapeutic gas delivery system is illustrated in FIG. **1**. The system generally includes an oxygen source **1** and a conserving device **2** for controlling the delivery of the oxygen to a patient **3**. The oxygen source **1** can be an oxygen concentrator, high pressure oxygen tank, or any other device that supplies oxygen. The conserving device **2** has a bolus delivery element **4**, a breath sensor **5**, and a controller **6**. The bolus delivery element **4** can include valves of the appropriate type and function. The breath sensor **5** is preferably a breath pressure sensor such as a transducer capable of detecting and measuring inspiratory breath pressure and transmitting signals to the controller **6**. The controller **6** includes an electronic circuit and a programmable microprocessor capable of determining the bolus volume and bolus timing based on the signals received from the breath sensor **5**. In one implementation, the controller **6** determines the bolus volume by controlling how long the delivery valve **4** is kept open in each delivery and controls the timing of the bolus by determining at which times the valve **4** is opened.

As will be described in greater detail below, the desired functionality of the therapeutic gas delivery system includes the ability to measure inspiratory breath pressure and to control the open timing of the delivery valve, thereby controlling the volume of the bolus. In certain embodiments, the system is configured to address difficulties and problems associated with delivering therapeutic gas to a patient during sleep.

Threshold Pressure Setting

The efficacy of elevating oxygen concentrations in the lungs is generally known to relate to how much oxygen is delivered in early (alveolar) inspiration. While the exact fraction of inspired gas may vary from patient to patient, in general, the bolus volume delivered during the first half of an inspiratory cycle is more significant in oxygenating the patient. Thus, conserving devices are preferably designed to deliver pulses of oxygen to the patient during the very early stages of each inspiratory cycle.

Typically, a conserving device triggers a bolus delivery when it detects a predetermined inspiratory pressure from the breath sensor. Thus, the term "threshold pressure" generally refers to the sensed inspiratory pressure at which a bolus delivery is triggered. In general, it is preferable to set the threshold pressure as high as possible to avoid triggering a bolus delivery based on false breath detection due to electrical signal noise or pressure noise in the cannula caused by patient activities. However, too high a setting can also render the therapy ineffective.

FIG. **2** is a graphic illustration of the relationship between the threshold pressure setting and the efficacy of the gas delivered. As shown in FIG. **2**, the bolus delivery profiles **202**A, **202**B for two different threshold pressure settings T_A and T_B are correlated to the pressure profile **204** of a patient's inspiratory cycle. Threshold pressure level T_A **202**A triggers delivery early enough to allow for full bolus delivery in the first half **206** of the inspiratory cycle. Threshold pressure level T_B **202**B, however, causes delivery of a significant portion of the bolus in the second half **208** of the inspiratory cycle, and thus is not as effective. Accordingly, when the threshold pressure level is set too high relatively to the inspiratory pressure of the very early stages of an inspiration cycle, a significant portion of the bolus is likely to be delivered during the second half of the inspiratory cycle which renders the therapy less effective.

Shallow Breathes During Sleep

Problems associated with high threshold pressure settings are particularly apparent in conventional gas delivery systems when the patient is asleep or in a state of inactivity. As shown in FIG. **3**, the inspiratory pressure profile **302** of a patient's breath during sleep may be much shallower than the inspiratory profile **304** of the patient's breath during normal activity. Thus, a threshold pressure value T_A **306**, which is effective during normal day activity, may be ineffective at night when the patient's is asleep. During sleep when the breaths are often shallower, the threshold pressure T_A may not be reached sufficiently early in the inspiratory cycle **302** to allow a significant portion of the bolus to be delivered in the first half **308** of the cycle. FIG. **3** shows that a night response to threshold pressure T_B **310** is equivalent to the day response to threshold pressure T_A **306**, although it is understood that the night bolus timing and volume do not have to exactly correspond to the day bolus to be effective.

Erratic Breathing During Sleep

During sleep, breath timing **402**, **406** may also be quite erratic. The time elapsed between successive breaths may vary greatly, which makes it difficult for conventional conservers to deliver the prescribed amount of oxygen to the patient over a period of time. In order to keep the overall gas delivered to the patient constant over time, bolus volume **404**, **408** may be adjusted as shown in FIG. **4**, such that after a longer time **406** between breaths, a larger bolus volume **408** is delivered.

The therapeutic gas delivery systems of the preferred embodiments have features designed to address one or more of the above-described problems typically associated with delivering therapeutic gas to a patient during sleep. This may be particularly important in optimizing the combined system

performance of the conserver in concert with the function of the device supplying the gas flow, especially in the case of devices such as oxygen concentrators in which the rate of gas flow delivery is limited by design.

Normal Activity Mode and Sleep Mode Threshold Pressure Settings

In one embodiment, as shown in FIG. **5**, the system has settings for switching between a "day" or "normal activity" mode **502** and a "night" or "sleep" mode **504**. A lower threshold pressure level or higher sensitivity is preferably used when the patient is sleeping. The bolus is preferably triggered at an earlier time in the inspiratory cycle, allowing for full bolus delivery before the first half of the cycle. Several implementations of this embodiment are possible. The patient may simply be given a user input to the controller, allowing for several different threshold pressure settings or sensitivities, user selectable, to be entered into the controller. The patient may choose a value to be used during normal activity in the day, and change to a lower value to be used at night when the patient is sleeping. Alternatively, either a "day" or "night" mode may be selected, with the sensitivities, A and B programmed into the controller by the patient's caregiver, or loaded at the factory. Although a lower threshold value is more susceptible to false triggers, a sleeping patient is typically quite still and less prone to generate pressure noise in the cannula, which may lead to false triggers. Thus, a higher nighttime sensitivity can be effective, especially if low electrical signal noise can be achieved.

Variable Bolus Volume in Response to Variations in Time Between Breaths

In another embodiment, the system is programmed to vary the bolus volume delivered in response to variations in the elapsed time between breaths, which addresses the erratic breathing pattern concerns described above. As shown in FIG. **6**A, the controller can be programmed to measure elapsed time between breaths, Δt, and apply a control gain G**1**, thereby delivering a bolus volume such that the average flow rate over time is nearly constant. However, FIG. **6**A shows that the bolus volume **602** may become quite large after long periods of elapsed time between breaths. The large boluses may cause discomfort for some patients. Moreover, in a case such as an oxygen concentrator in which the gas supply stores a volume of gas at pressure in an accumulator, large swings in bolus volume can result in swings in the stored pressure in the accumulator. This can be destructive for both the oxygen generation process and for the repeatable delivery of the subsequent bolus, which is driven by the pressure in the accumulator. To address this problem, FIG. **6**B shows an alternative embodiment in which a proportional-integral-derivative (PID) algorithm is applied to Δt to determine the bolus volume. This has the effect of smoothing out the volume variation while still keeping overall nearly constant flow rate.

Auto-Fire Mode

In yet another embodiment, the system is capable of operating in an auto-fire mode. The term "auto-fire" refers to delivering a constant volume bolus at fixed time intervals independent of the breathing pattern. This feature is particularly effective when breath period and inspiratory pressure profiles are very erratic, or for mouth breathers. As shown in FIG. **7**, the controller may be set in a mode in which the conserver simply "auto-fires" a constant volume bolus at a fixed period, not tied to an actual breath. This embodiment relies on the patient entraining oxygen rich air in the cannula into the lungs. If taken to an extreme of very small boluses delivered with no time gap between boluses, this embodiment approaches the performance of a continuous flow device. However, because in this embodiment the gas is delivered in short bursts, more of it penetrates the nasal passages where it can be entrained with inspiration. This allows a smaller overall volume of gas to be delivered.

Adaptive Control Responsive to Multiple Breath Parameters

In another embodiment as illustrated in FIG. **8**, the system has adaptive controls designed to vary the bolus delivery in response to a number of breath parameters. This feature effectively addresses many of the above issues at the same time, while improving immunity to false, ineffective triggers. As shown in FIG. **8**, upon delivery of a bolus **800**, the controller enters a "blind time" **802** where it will not accept a breath trigger. The blind time **802** prevents any ineffective bolus delivery for a period of the breath and some period, in the range of about 0.5-3.0 seconds, typically about 1.5 seconds. Upon the end of the blind time **802**, the controller sets the trigger sensitivity at a low, noise immune, level, P_H **804**. The controller then ramps the trigger sensitivity over a time, typically 1-2 seconds to a higher sensitivity, P_L **806**. If after a time, typically about 2-3 seconds after a breath is anticipated, no breath is detected even at the high sensitivity, a bolus is auto-fired. Any suitable curve may be used instead of a linear ramp as shown in FIG. **8**. The inventors have found an exponential ramp is effective as well.

As an example of the system of FIG. **8**, for a typical oxygen patient breathing about 15 times per minute, a new inspiratory cycle is initiated every 4 seconds. After a bolus is delivered, the conserver spends the next 1.5 seconds blind, during which time all sensor input is ignored. The threshold vacuum pressure may start out at about 0.30 cm of water at that point. Because the anticipated breathing period is 4.0 seconds (calculated from average breathing rates), the threshold pressure is controllably decreased over the next 2.25 seconds (1.5-3.75 seconds from last bolus) until it reaches a higher sensitivity level of about 0.08 cm of water. If, after an additional 2.75 seconds (6.5 seconds from last bolus) no breath has been detected, a bolus is automatically delivered.

In yet another embodiment as shown in FIG. **9**, if an auto-fire event took place on the last cycle, the controller may shorten the time **902** between the end of the blind period **802** to when the auto-fire takes place again. If auto-fire happens on a number of successive cycles, the controller may revert to the fixed auto-fire mode of FIG. **7**. The controller may also adjust bolus volume in any of these scenarios to account for variation in breath period. In the event of successive auto-fires, the controller may alternatively be programmed to reduce P_L until reliable breath detection resumes without auto-fires.

Alternatively, the controller may decrease the blind time. If the blind time is decreased, the period during which a breath is detected increases, making it more likely to detect a breath. Decreasing the blind time may be used alone or in concert with reducing P_L **904** to try to return from auto-fire mode to breath detection. In certain embodiments, there is a practical limit to how much the blind time may be decreased which is set by the design of the pressure sensor electronic interface. For example, in an oxygen concentrator design used by the inventors, the sensor interface is zeroed during the blind time. Thus, if the blind time is set too short, the zeroing will not be complete, having the effect of actually reducing the sensitivity of breath detection. In the case of an apnea event, the controller may be programmed to enter continuous auto-fire mode after a predetermined time, and to revert to one of the above modes on set intervals to re-enter normal sleep breathing cycles.

A Method of Determining Bolus Volume and Timing

FIG. **10** is a flow chart illustrating a preferred method of determining bolus volume and timing in the delivery of a therapeutic gas to a patient. As shown in FIG. **10**, once a bolus is delivered in Step A **1100**, the systems enters a blind time T_{blind} of about 1500 ms in step B **1102**. During this time, the system performs several computations in Step C **1104**,

including determining the average breathing cycle time T_{cycle}, the appropriate high and low threshold pressure limits, if not fixed, and the time during which the threshold pressure will be reduced, T_{ramp}. In Step D **1106**, the system determines whether the previous bolus was auto-fired. If it was, then the ramp time is reduced from its previous value in step E **1108**. Preferably, in no case is the time before the system auto-fires allowed to encroach on the blind time plus some nominal period, such that for some duration on each breathing cycle a breath may be detected. If the bolus was fired in response to a breath detection, then the ramp period is selected in Step F **1110** such that it is somewhat less than the period between the end of the blind time and the end of the expected breathing cycle (T_{cycle}–T_{blind}). This allows a short period before the expected next breath during which the threshold pressure is at its lowest level. Once the blind time passes, the system threshold will be selected as either a decreasing function of time varying between a high and low value in Step I **1112**, or as the lowest value in Step H **1114** if the ramp time has passed. The system monitors the pressure signal in Step J **1116**, and if a signal that meets the threshold requirements is met, the system fires a bolus in response in Steps L **1118**, N **1120**, and A **1100**. If the signal does not exceed the threshold requirements before some time greater than the expected breathing cycle T_{cycle}, then a bolus is automatically triggered in Steps M **1122**, N **1120**, and A **1100**. The cycle then begins again.

Advantageously, the preferred embodiments of the present invention provide a wide range of bolus control options, which can allow a practitioner the flexibility to tailor the bolus delivery patterns to maintain effective therapy for many different types of patient sleep breathing scenarios. These modes may also be useful for daytime operations as well.

Although the foregoing description of the preferred embodiments of the present invention has shown, described and pointed out the fundamental novel features of the invention, it will be understood that various omissions, substitutions, and changes in the form of the details of the invention as illustrated as well the uses thereof, may be made by those skilled in the art, without departing from the spirit of the invention. Consequently, the scope of the invention should not be limited to the foregoing discussions.

What is claimed is:

1. A system for delivering therapeutic breathing gas to a patient, comprising:

a gas source;

a conserver between the gas source and the patient;

a sensor for detecting patient breath events and measuring the parameters of the breath events, said parameters including breath pressure level;

processor and control elements for acquiring signals from the sensor and controlling the delivery of gas to the patient, wherein the system supports at least one mode of operation such that a threshold breath pressure level detected by the sensor, which causes the processor and control elements to deliver a volume of gas to the patient, may be user selectable such that the volume of gas is delivered to the patient when the patient's threshold breath pressure level is at the level selected by the user; and

wherein the system provides a plurality of user selectable threshold pressure levels, said threshold pressure levels comprising a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal.

2. The system of claim **1**, wherein the different levels of threshold breath pressure comprise two user-selectable levels, representing a night mode and a day mode, and the actual values of each level are determined by the patient's caregiver.

3. The system of claim **1**, wherein the gas is oxygen and the gas source is an oxygen concentrator.

4. A system for delivering therapeutic breathing gas to a patient, comprising:

a gas source;

a conserver between the gas source and the patient;

a sensor for detecting patient breath events and measuring the parameters of the breath events such as breath pressure level; and

processor and control elements for acquiring signals from the sensor and controlling the delivery of gas to the patient, wherein the system supports at least one auto-fire mode of operation such that the processor and control elements measure the time since the last breath detected by the sensor, and if no breath is detected after a predetermined time period and no gas is delivered to the patient in this predetermined time period, a volume of gas is delivered to the patient automatically.

5. The system of claim **4**, wherein after the automatic delivery of the volume of gas, the processor reduces the breath pressure level which will trigger bolus delivery for the next breath cycle.

6. The system of claim **4**, wherein the processor reduces the breath period for the next breath cycle.

7. The system of claim **4**, wherein the gas is oxygen and the gas source is an oxygen concentrator.

8. An apparatus for delivering a series of boluses of gas to a patient, comprising:

a gas source;

a conserver between the gas source and the patient;

a sensor which detects breaths by the patient; and

a controller which receives signals from the sensor and triggers delivery of gas boluses in accordance with predefined triggering parameters, said controller determining the time elapsed since the last bolus was triggered, and altering the triggering parameters as a function of said elapsed time.

9. The apparatus of claim **8**, wherein said triggering parameters comprise a blind period during which said triggering delivery of gas boluses is disabled.

10. The apparatus of claim **8**, wherein said triggering parameters comprises a threshold inspiratory pressure of the patient.

11. The apparatus of claim **8**, wherein the controller triggers an auto-fire bolus when said elapsed time is greater than a predetermined time.

12. The apparatus of claim **8**, wherein each of the said triggering parameters is a function of the triggering parameters of one or more boluses previously delivered.

* * * * *

COPY OF DECISION ON APPEAL

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INOVA LABS, INC.
Requester/Appellant

v.

INOGEN, INC.
Patent Owner/Respondent

Appeal 2014-001158
Reexamination Control 95/001,885
US Patent No. 7,841,343[1]
Technology Center 3900

Before: JOHN C. KERINS, RAE LYNN P. GUEST, and BRETT C. MARTIN, *Administrative Patent Judges*.

MARTIN, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] Issued to Deane et al. on November 30, 2010 (hereinafter referred to as the "'343 patent").

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Oral arguments occurred on March 19, 2014, a written transcript of which will be entered into the electronic record in due course.

We AFFIRM.

THE INVENTION

Patent Owner's invention is directed generally to "systems and methods for delivering therapeutic gas to patients, and in particular, relates to such systems and methods in which the gas delivery is tailored to the patient's breathing pattern." Spec., col. 1, ll. 13-16. Claim 1, reproduced below, is illustrative of the claimed subject matter:

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> a conserver between the gas source and the patient;
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> a sensor for detecting patient breath events and measuring the parameters of the breath events, said parameters including breath pressure level;
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> processor and control elements for acquiring signals from the sensor and controlling the delivery of gas to the patient, wherein the system supports at least one mode of operation such that a threshold breath pressure level detected by the sensor, which causes the processor and control elements to deliver a volume of gas to the patient, may be user selectable such that the volume of gas is delivered to the patient when the patient's threshold breath pressure level is at the level selected by the user; and

> wherein the system provides a plurality of user selectable threshold pressure levels, said threshold pressure levels comprising a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal.

REFERENCES

The prior art relied upon by the Requester in the proposed rejections of the claims on appeal is:

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1. Claims 8-12 under 35 U.S.C. § 102(b) as anticipated by Hakkinen. RAN 6; App. Br. 3.

2. Claims 1-3 and 8-17 under 35 U.S.C. § 103(a) as unpatentable over Hakkinen and Admitted Prior Art ("APA"). RAN 8; App. Br. 3.

3. Claims 13 and 14 under 35 U.S.C. § 103(a) as unpatentable over Hakkinen, APA, Chua, Callahan, and Moseley. RAN 18; App. Br. 3.

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9. Claims 8-12 under 35 U.S.C. § 103(a) as unpatentable over Kloeppel and Chua (or Chua and Kloeppel). RAN 21; App. Br. 4.

ANALYSIS

Hakkinen

As noted *supra*, many of the rejections rely on Hakkinen and therefore stand or fall depending on our determination as to what Hakkinen does or does not teach. Accordingly, we will address Patent Owner's arguments with respect to Hakkinen first.

Claim 8

According to the Requester, Hakkinen discloses "altering triggering parameters as a function of said elapsed time" because it teaches that "the computer 100 works to control the oxygen supply valves in response to inhalation pressure … and via a timing mechanism." App. Br. 10. As Patent Owner points out, however, "the sentence in Hakkinen the Requester relied on has nothing to do with altering triggering parameters" and "merely describes that the opening of the delivery valves can be timed as desired and appropriate from a therapeutic point of view." Resp. Br. 5. Quoting Patent Owner's earlier arguments during the reexamination, the Examiner notes that "[t]he Hakkinen apnea timer is a simple override feature that causes the

delivery valve to open if no breath is detected within a determined apnea period." RAN 7. We agree with Patent Owner and the Examiner that the timing mechanism described in Hakkinen does not alter triggering parameters as recited in claim 8.

Claim 1

Regarding claim 1, Requester asserts that Hakkinen teaches the claimed user-selectable threshold pressure levels via the fact that Hakkinen contains a potentiometer that can control the triggering sensitivity of the device. Hakkinen Spec., col. 10:8-18. Claim 1 specifically recites "the system provides a plurality of *user selectable* threshold pressure levels, said threshold pressure levels comprising a lower level adapted to trigger delivery of gas to the user when the user is asleep or in a state of inactivity such that the user's breath is shallower than normal" (emphasis added). We agree with Patent Owner that the mere presence of a potentiometer does not teach this claimed limitation. Hakkinen does not state anywhere that the potentiometer is a device intended to be used by the user/patient[2] to adjust settings during operation. Accordingly, we are persuaded that it does not qualify as a "user selectable" device.

[2] During oral argument, Requester stated that "user" and "patient" must be different people, thus allowing the "user" to be a technician, for example, at a factory because if the Patent Owner wanted the user to be the patient, the claim should have simply recited "patient" throughout. We disagree with this assertion because claim 1 specifically contains limitations such as "when the *user* is asleep" and "the *user's* breath" that explain that the user is intended to be the patient, i.e. the user of the device, and not a factory technician.

Requester asserts, for example, that the potentiometer "can just be a knob" (App. Br. 14) to allow for variability between daytime and nighttime settings. Requester also asserts that "if Hakkinen wanted to limit the potentiometer to 'factory only' use, then he would have stated as much." App. Br. 11. The corollary to Requester's assertion is that had Hakkinen intended for the potentiometer to be a user interface for providing adjustability, then he would have stated as much as well. Without determining whether or not Hakkinen is limited to factory adjustment, the proper inquiry is whether the potentiometer is capable of *user* adjustment, and Hakkinen is silent regarding whether a user would use the potentiometer to adjust the settings as claimed. There simply is insufficient disclosure in Hakkinen regarding the function of the potentiometer to glean that it could operate to allow *user selectability* in the manner suggested by Requester to meet the claimed limitations.

Accordingly, we do not agree with Requester that Hakkinen teaches either of the limitations at issue in sole independent claims 1 or 8. As such all of the rejections involving Hakkinen are deficient as set forth by the Examiner and argued by Patent Owner. We, therefore, sustain the Examiner's non-adoption of rejections 1-6 and 8 above.

Chua

Requester asserts that Chua teaches the claimed controller capable of altering the threshold inspiratory pressure level as a function of elapsed time, as required by claim 8, due to its disclosure that "[t]he calculated quantity of the gaseous fluid to be delivered to the patient is predicated upon the immediate breathing cycle." App. Br. 22 (citing Chua Spec., col. 12, ll. 57-

66). According to Requester, Chua teaches monitoring "a breathing rate (*See*, FIG. 5B), which is a known function of time (i.e., breaths/min)." *Id.* As Patent Owner points out, however, "the calculated quantity of gas has nothing to do with altering the triggering parameters [i.e., the threshold inspiratory pressure level] as a function of the elapsed time." Resp. Br. 12. Patent Owner further notes that "Chua is directed to adjusting the timing and amount of oxygen to be delivered (Chua 16:60) during a breathing cycle" and that "Chua does not adjust the threshold inhalation pressure for triggering bolus delivery." Resp. Br. 10. Patent Owner also states that "Chua is directed to delivering oxygen at a desired point within a breathing cycle and varying the quantity of gas delivered within a breathing cycle because of different needs." *Id.* We further note that the monitor breathing rate step in Figure 5B is not related to altering the threshold inspiratory pressure level, but rather is designed to activate an alarm when no inhalation is detected. Chua, col. 21, ll. 15-18. We agree with Patent Owner that Chua's disclosure is not the same as the claimed altering of triggering parameters relating to changing the threshold inspiratory pressure level as a function of elapsed time as recited in claim 8. Accordingly, we sustain the Examiner's decision not to adopt rejections 7 and 9 above.

Declarations

Requester argues at length regarding the inadequacy of Patent Owner's declarations. *See* App. Br. 6-10; Reb. Br. 3-4. First, we agree with Patent Owner that Requester errs in the assertion that the declarations are the sole basis for the Examiner's non-adoption of the proposed rejections. As Patent Owner notes, "nowhere in the ACP does it state that the reversal (in

adoption of Requester's rejections) of [c]laims 8-12 is solely based on the declarations." Resp. Br. 5. Furthermore, we disagree with Requester's characterization of Patent Owner's declarations as "personal opinions" not worthy of any weight. *See, e.g.,* App. Br. 5. Declarations are, by their nature, often the opinions of experts in the field of endeavor and are often precisely the kind of evidence utilized to *assist* in making determinations regarding patentability.

Requester further asserts that Mr. Hakkinen's declaration is improper because he did not read the '343 patent. *See* App. Br. 6. Whether or not Mr. Hakkinen read the '343 patent is irrelevant as to Mr. Hakkinen's knowledge of his own patent, which is the subject of much of his declaration. Also, Requester misapplies *Standard Oil*[3] in asserting that the Hakkinen declaration is irrelevant. *See id.* The inventor's skill versus one of ordinary skill is not at issue with regard to the declaration. Mr. Hakkinen merely has expressed his knowledge as to what his invention was and how that relates to the disclosure of his own patent. In sum, we see no basis to ignore Patent Owner's declarations entirely, as Requester recommends. Furthermore, the declarations are but one factor in assessing the adequacy of the rejections and are by no means the sole basis for the non-adoption of the proposed rejections.

DECISION

For the above reasons, we AFFIRM the Examiner's decision not to adopt the Requester's proposed rejections at issue in this appeal.

---

[3] *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448 (Fed. Cir. 1985).

Requests for extensions of time in this *inter partes* reexamination proceeding are governed by 37 C.F.R. §§ 1.956 and 41.77(g).

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AFFIRMED

PATENT OWNER:

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THIRD PARTY REQUESTER:

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INOVA LABS, INC.
Requester/Appellant

v.

INOGEN, INC.
Patent Owner/Respondent

Appeal 2014-001158
Reexamination Control 95/001,885
US Patent No. 7,841,343[1]
Technology Center 3900

Before: JOHN C. KERINS, RAE LYNN P. GUEST, and BRETT C. MARTIN, *Administrative Patent Judges*.

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AFFIRMED

PATENT OWNER:

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